

Effectiveness of N95 Masks against SARS-CoV-2: Performance Efficiency, Concerns, and Future Directions

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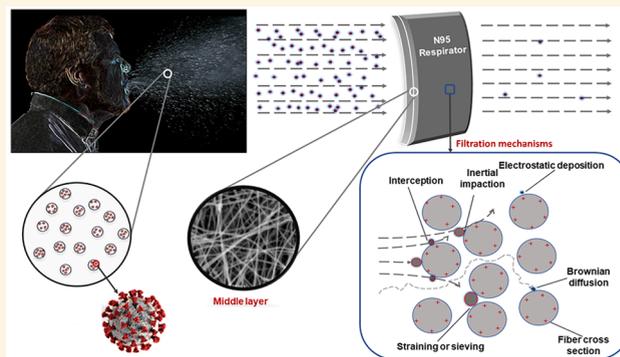
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ABSTRACT: The coronavirus disease 2019 (COVID-19) epidemic, which is caused by novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has continued to spread around the world since December 2019. Healthcare workers and other medical first responders in particular need personal protective equipment to protect their respiratory system from airborne particulates, in addition to liquid splashes to the face. N95 respirator have become a critical component for reducing SARS-CoV-2 transmission and controlling the scale of the COVID-19 pandemic. However, a major dispute concerning the protective performance of N95 respirators has erupted, with a myriad of healthcare workers affected despite wearing N95 masks. This article reviews the most recent updates about the performance of N95 respirators in protecting against the SARS-CoV-2 virus in the present pandemic situation. A brief overview of the manufacturing methods, air filtration mechanisms, stability, and reusability of the mask is provided. A detailed performance evaluation of the mask is studied from an engineering point of view. This Review also reports on a comparative study about the protective performance of all commercially available surgical and respiratory masks used to combat the spread of COVID-19. With the aim of protecting healthcare providers more efficiently, we suggest some potential directions for the development of this respiratory mask that improve the performance efficiency of the mask.

KEYWORDS: *surgical mask, reusability, filtration mechanism, coronavirus 2, COVID-19*



1. INTRODUCTION

Since the World Health Organization (WHO) declared the current novel COVID-19 epidemic a public health emergency on January 30, 2020, the pandemic has spread, with a distinctive subexponential increase in confirmed cases throughout the world.^{1,2} Consequently, on March 11, 2020, the WHO declared it a pandemic after the identification of more than 118 000 cases in 114 countries.³ As of July 09, 2020, over 12 million COVID-19 cases and almost 551 000 deaths in 212 countries have been reported worldwide.⁴ The quick spread and contagious nature of the disease put healthcare professionals everywhere in a situation of unprecedented vulnerability, and they have had to make impossible decisions and work under extreme pressure. According to the Centers for Disease Control and Prevention (CDC), approximately 9200 healthcare providers in the USA tested positive for the coronavirus, with 27 fatalities, as of April 15, 2020, and the real number is likely far higher than the reported cases.⁵ For some states, the rates of healthcare worker illness have risen as high as 20%.⁵ In China, an estimated 3000 healthcare workers have been infected along with their family members, and at least 22 have died.⁶ The inadequate supply of protective materials, excessive workloads, and the extremely

transmissible nature of this disease are responsible for the very high case tally.

Biological aerosol particles derived from viruses, bacterial cells, bacterial and fungal spores, algae, protozoa, fragments, and pollen grains are responsible for major infectious diseases.⁷ Virus particles, being small in size, can easily enter the human respiratory system and may cause diseases such as colds, the flu, measles, mumps, pneumonia, rubella, or chickenpox.^{7–9} All viruses do not have the same infective dose, and the adverse health effects of these particles depend on the number of inhaled particles, not on their mass. Coronaviruses are named for their resemblance to the crownlike corona observed during a total solar eclipse when they are under an electron microscope. These are nonsegmented, enveloped, positive-sense, and single-stranded RNA viruses and are responsible for most viral illness.^{10–14} The virus responsible for the current COVID-19

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pandemic is named “severe acute respiratory syndrome SARS-CoV-2” (originally called novel coronavirus) since it is related to the SARS virus that caused an epidemic in China in 2002–2003. Similar to most viruses, coronaviruses range from 4 to 1000 nm and are rarely observed as individual particles, but they are typically expelled from the body along with water, and other components as large droplets and aerosols.^{15,16} SARS-CoV-2 has been observed in aerosolized particles over a range of sizes from 250 to 500 nm.^{15,17} These viruses are transmitted via person-to-person contact, respiratory droplets, aerosolization, and surface transmission.^{11,18} The most common transmission routes include breathing, sneezing, coughing, or talking and any other activities associated with virus aerosolization.^{19,20} Researchers found strong evidence to suggest the possibility of airborne transmission through aerosolized particles beyond 6 ft.²¹ The highly obvious pathways for human entrance are the mouth, nose, and sometimes the eyes. Hence, wearing a respiratory protective device in a higher-risk environment would aid in preventing virus-containing droplets from spreading to the environment.

In 1995, after several consecutive incidences of tuberculosis bacteria (TB) transmission to physicians, nurses, and other healthcare providers from TB patients, the National Institute for Occupational Safety and Health (NIOSH) issued a new regulation for particulate respirators.²² The new regulations require that all certified particulate respirators have at least 95% efficiency at the most penetrating particle size (100–300 nm) while being tested at a heavy workload inhalation flow rate of 85 L/min.²³ Since 1995, many filtering facepiece respirators (FFRs) have entered the market. To date, NIOSH tests and approves nine different categories of FFR. Each of the N, R, and P series is approved at different collection efficiencies (95, 99, and 100).²⁴ In the latest pandemic situation, N95 respirators have been in greatest demand for preventing transmission of SARS-CoV-2 and are widely recommended throughout the world to protect healthcare workers against COVID-19.¹¹ N95 respirators produced by a variety of companies show different efficiencies in the removal of most penetrating particle sizes; notably, each mask is at least 95% efficient in the separation of NaCl particles of the aforementioned size range.^{25,26} The particle removal efficiency of N95 respirators increases with increasing particle sizes and reaches approximately 99.5% or higher at approximately 750 nm.

N95 respirators are developed to minimize facial seal leakage through a tight fit and to prevent the inhalation of small airborne particles. Nevertheless, there is evidence of declining performance efficiency due to seal leakage of the mask; even body movements during nursing processes may increase the risk of face seal leakage.²⁷ Although most of the published reports claim a better performance of N95 respirators than those of traditional surgical or medical masks to protect against viral infections,^{28–31} some research groups have claimed differently. In a clinical study, Radonovich et al. and Loeb et al. compared the effectiveness of N95 respirators and medical masks (or surgical masks) in preventing influenza and other viral respiratory infections among outpatient healthcare personnel (HCP) but did not find any substantial difference in the frequency of laboratory-confirmed influenza.^{28,29} Many reports identified both mask types as having a range of filtration efficiencies; however, N95 masks offer better protection against particles of sizes similar to those of viruses.^{32,33} Because of the lack of high-quality studies on the healthcare setup, the advocacy of mask types cannot be supported or nullified by the current evidence.

That is why it appears that, during current pandemic management, many recommendations made by world-renowned organizations were conflicting and were shown to be invalid, as they were made based on limited epidemiological data on mask effectiveness against COVID-19.

Evaluations on the filtration efficiency of N95 respirators are a challenging task that requires the generation of a large amount of small particles down to single-digit nanometers and the accurate quantification of these particles.³⁴ N95 respirators are usually tested against nonbiological particles as the challenge aerosol; however, the penetration of biologic particles through the respirator filters may vary from that of their corresponding nonbiological simulations.⁷ Several incidents of COVID-19-positive cases have been reported by healthcare providers after wearing N95 masks during exposure to patients.³⁵

Despite the lack of trustworthy data and evidence, a trend in favor of N95 respirators has been observed in preventing SARS-CoV-2. Some recent systematic reviews have addressed the role of N95 respirators in protecting against COVID-19.^{4,5,33,36–38} Most of these reviews compared the performance of different types of masks and analyzed their medical aspects. None of them neither discussed the efficiency of N95 respirators from an engineering point of view nor provided any effective suggestion to improve the performance of these respirators. Hence, a systematic review is needed to decide the best strategy for developing a new N95-based respiratory protection system that supports healthcare systems in any catastrophic pandemic situation similar to COVID-19. Here, we reviewed the literature on the filtration efficiency of N95 masks for airborne viruses with a focus on their performance in preventing COVID-19. The Review starts with an overview of the current COVID-19 situation and the importance of providing a sufficient supply of proper protective equipment for front-line workers. The fabrication methods and filtration mechanisms of N95 have been introduced with an evaluation of reports on the performance of N95 masks. A comparison with commercially available masks or respirators that can be used in coronavirus filtration systems is also provided. Future approaches have been discussed to improve the protective performance of the mask and to develop an appropriate methodology to reuse them without compromising their barrier properties.

2. SARS-CoV-2: ORIGIN, TRANSMISSION, PREVALENCE, AND PROTECTION

Since the initial outbreak, the novel coronavirus (nCoV) pandemic has spread globally, shutting down and shattering businesses worldwide by negatively changing human lifestyle. This is the third CoV that appeared after severe acute respiratory syndrome coronavirus (SARS-CoV) in 2002 and Middle East acute respiratory syndrome coronavirus (MERS-CoV) in 2012 and is referred to as SARS-CoV-2 by the International Committee on Taxonomy of Viruses.³⁹ The disease originating from this virus is named COVID-19.^{40,41}

2.1. Origin and Modes of Transmission of SARS-CoV-2.

Similar to all types of CoVs, SARS-CoV-2 also belongs to the subfamily *Coronavirinae* under the *Coronaviridae* family.⁴² Depending on genomic structures and phylogenetic relationships, *Coronavirinae* is further subdivided into four genera. (i) Alpha (α)-coronavirus includes the human coronaviruses HCoV-229E and HCoV-NL63. (ii) Beta (β)-coronavirus contains HCoV-OC43, HCoV-HKU1, SARS-CoV, MERS-CoV, and SARS-CoV-2. (iii) Gamma (γ)-coronavirus is obtained from whales and birds, and (iv) delta (δ)-coronavirus

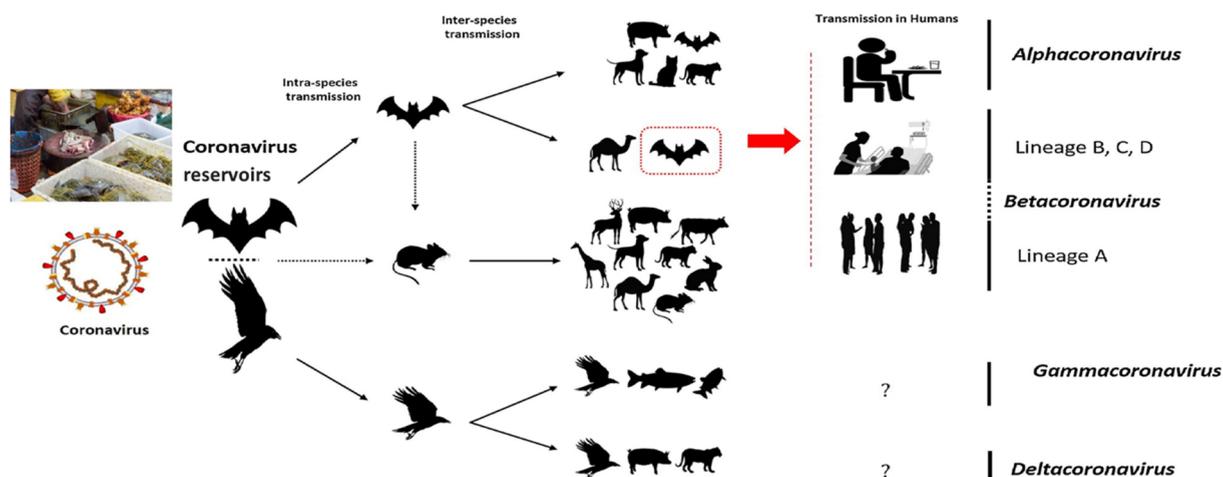


Figure 1. Mode of transmission of coronaviruses from the key hosts (each red dotted box and arrow represents the suspected hosts of SARS-CoV-2). Confirmed viral transfer from the host is represented by solid black arrows, and the possibility of transfer is represented by dotted black arrows. Adapted with permission from ref 47. Copyright 2020 Elsevier.

is isolated from pigs and birds.⁴² Among the β -CoVs, HKU1 and OC43 are responsible for mild respiratory diseases in humans, whereas SARS-CoV, MERS-CoV, and SARS-CoV-2 are responsible for acute respiratory diseases.

The current sequence database shows that all human CoVs originate from animals. Bats are the natural reservoirs of SARS-CoV, MERS-CoV, and HCoV-NL63, whereas rodents are responsible for HCoV-OC43, HCoV-HKU1, and HCoV-229E.⁴³ Research on SARS-CoV-2 suggested that the key reservoir of this virus is also bats, as it shows 96% similarity at the whole genome level to a bat-originated coronavirus.⁴⁴ Homologous recombination studies revealed that receptor binding by the glycoproteins of SARS-CoV-2 has developed in SARS-CoV (70% similarity in genetic sequence) and an unknown β -CoV.^{12,13,45} Domestic animals may play an important role in transmitting CoVs from natural reservoirs to humans as intermediate hosts. The transmission of SARS-CoV-2 from bats to humans is still unknown. However, several studies have indicated that minks and pangolins could be intermediate hosts.^{12,46} The transmission of coronaviruses from key reservoirs to humans is summarized in Figure 1.

Structurally, SARS-CoV-2 consists of positively charged single-stranded RNA with sizes ranging from 8100 to 9600 nm in length and from 60 to 160 nm in diameter. The structural proteins of SARS-CoV-2 are encoded by spike (S), envelope (E), membrane (m), and nucleocapsid (N) structural genes (Figure 2). Spike proteins have a 3D structure in the receptor-binding domain region to maintain van der Waals forces.⁴⁸ The presence of 394 glutamine residues in this region is recognized by critical lysine 31 residues on the human angiotensin-converting enzyme 2 (ACE2) receptor, which is specifically available in human lung cells.⁴⁹ SARS-CoV-2 also expresses other polyproteins, nucleoproteins, and membrane proteins, such as RNA polymerase, 3-chymotrypsin-like protease, papain-like protease, helicase, glycoprotein, and accessory proteins.¹³ The mechanism for entry into host cells is the same for SARS-CoV and SARS-CoV-2, as both use the same ACE2 cell receptor.^{48,50} The constant development of transcription error and RNA-dependent RNA polymerase (RdRP) jumps results in high recombination rates in SARS-CoV-2. Moreover, it has a high mutation rate, and it is referred to as a zoonotic pathogen as it originally came from an animal, likely a bat.

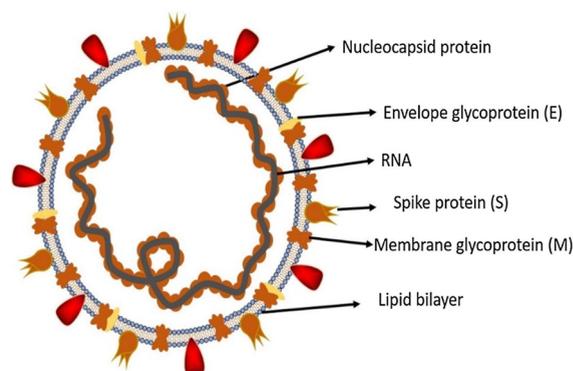


Figure 2. Structure of human coronavirus. All coronaviruses bear specific genes in their ORF1 downstream regions that encode proteins for viral replication. The spike glycoproteins on the outer surface of the coronaviruses are responsible for the entry of the virus into the host cell. Adapted with permission from ref 47. Copyright 2020 Elsevier.

In terms of spreading, the higher transmission ability of SARS-CoV-2 is observed due to a genetic recombination event at the S protein in the coronavirus's receptor-binding domain. According to the CDC, COVID-19 is still new, and the transmission of this virus is not fully understood. An infected person can affect any other person present within a range of 6 ft through large respiratory droplets (>5000 nm) laden with viruses coming from his coughs, sneezes, or talking. These droplets can settle in the mouths and lungs of other people through inhaled air. Due to their large size, respiratory droplets remain in the air for a short time and cannot travel more than 3.3 ft (1 m).¹⁸ This idea guided the CDC to offer the advice to maintain at least a 6 ft distance from other people to prevent the spread of COVID-19.¹² Few studies have addressed the absence of nosocomial infections among patients with COVID-19.⁵¹ Notably, small aerosolized droplets laden with viruses (<5000 nm) remain in the air for a longer time and travel a long distance (more than 3.3 ft).⁵² When suspended in the air over long distances and time periods, these infectious agents lead to airborne transmission.⁵³ The different routes of SARS-CoV-2 transmission are summarized in Table 1.

Depending on this range, some reports have already suggested that 6 ft is not enough to prevent viral spread.⁵⁴ The maximum

Table 1. Commonly Accepted SARS-CoV-2 Routes of Transmission

routes of transmission	particle involved with transmission characteristics	pathways of transmission
Contact		
direct		transmission through one infected person to another person; self-inoculation of mucous membranes by contaminated hands
indirect		transmission through contaminated intermediate objects
Airborne		
droplets	droplets	transmission within short-range
	remain in air for short periods	direct inoculation of person through coughing/sneezing/breathing of infected person
	spread over short distances (<1 m)	deposition on mucous membranes and upper respiratory tracts
aerosols	aerosols, droplet nuclei	transmission within long-range
	remain in air for long time	inhalation of aerosols
	spread over long distances (>1 m)	deposition along the respiratory tracts, including local airways

distance for SARS-CoV-2 aerosol spreading has been found to be approximately 13.1 ft (4 m)⁵⁵ in some specific settings and circumstances, such as the ICU and wards of a hospital. As a result, surface transmission plays a role in facilitating the spread of viruses. To observe this movement, a report has suggested that the virus can live on surfaces such as plastics and metals for 2–3 days and on cardboard for 4 h;⁵⁵ thus, touching contaminated objects and surfaces and then touching the nose, eyes, or mouth enhance the spread of the virus. Moreover, a range of clinical features from an asymptomatic course requires hospitalization in the intensive care unit; infections in respiratory, gastrointestinal, hepatic, and neurologic systems have been observed due to the presence of SARS-CoV-2 in humans.^{56–58}

The routes of transmission and further analyses of hospital environments have highlighted the vulnerability of frontline workers to COVID-19 infection. To understand the potential environmental transmission risk of SARS-CoV-2, surface air samples, high-volume air samples, and low-volume personal air samples were taken into consideration.^{5,55,59} The presence of the virus in the hospital environment is listed in Table 2.

Table 2. Presence of Virus Found on Different Surfaces and Personal Items in Hospitals

surface/object	positivity rate of SARS-CoV-2	ref
computer mouse	intensive care unit (ICU) 75%; general ward (GW) 20%	55
trash cans	ICU 60%; GW 0%	55
sickbed handrails	ICU 42.9%; GW 0%	55
doorknobs	GW 8.3%	55
cellular phones	83.3%	59
remote controls for in-room TVs	64.7%	59
toilets	81.0%	59
room surfaces	80.4%	59
bedside tables and bed rails	75.0%	59
window ledges	81.8%	59

Early in the public emergency, there is a lack of specific treatments (e.g., appropriate vaccination) against the infection. Thus, community mitigation or nonpharmaceutical interventions are effective ways to prevent COVID-19, such as using a face mask, frequently cleaning hands, and maintaining social distance. Personal protective equipment (PPE) played an important role in lessening the occupational risk of respiratory infection.⁶⁰ However, to mitigate the effects of the virus on public health, vaccines have been developed rapidly. The first clinical trial for a SARS-CoV-2 vaccine began in March 2020. With the global demand for 16 billion vaccine doses, around 2.21 billion people have already been fully vaccinated.⁶¹

2.2. Face Masks and Respirators: Types and Classification. Face masks have become an emblem for respiratory protection in fighting against SARS-CoV-2. Many types of face masks and respirators are available on the market. Therefore, the choice of an effective face protection device is a critical factor for slowing down the spread of this virus.⁶² The Food and Drug Administration (FDA) has authorized the following types of masks or respirators in U.S. healthcare settings.

2.2.1. Face Masks. Face masks are loosely fitted devices that cannot avoid leakage around the mouth upon breathing. These are commonly made of single-layer fabrics including cotton, silk, chiffon, flannel, various synthetics, and their combinations; however, the efficiencies improved when multiple layers are used with a combination of fabrics.⁶³ They only provide a physical barrier against large respiratory droplets.⁶⁴ Usually, these devices are worn by suspected or confirmed COVID-19 patients to prevent the spreading of the droplets generated by the wearer in accordance with CDC recommendations.⁶⁵ However, they are not approved by NIOSH.

2.2.2. Surgical Masks. These are also loose-fitting and do not prevent leakage around the mouth upon inhalation. They are fluid-resistant and provide a physical barrier against body fluids and other hazardous fluids. They are not considered a form of respiratory protection. The FDA classified these masks as medical devices.

2.2.3. Respirators. A personal protective device that covers the nose and mouth and is used to reduce the wearer's risk of inhaling hazardous airborne particles (including dust particles and infectious agents), gases, or vapors. Different types of respirators are available including (i) particulate respirators, which filter out airborne particles; (ii) gas masks, which filter out chemicals and gases; (iii) airline respirators, which utilize compressed air from a remote source; and (iv) self-contained breathing apparatuses which have their own air supply.⁶⁶ Particulate respirators are also known as air-purifying respirators (APRs) as they can filter out the particles from air. Since bacteria and viruses are airborne biological particles, they can be filtered by particulate respirators. The particulate respirators are further divided as follows:

- **Disposable.** It is discarded when it becomes unsuitable for further use due to excessive resistance, sorbent exhaustion, or physical damage.
- **Reusable or Elastomeric.** This item can be reused by cleaning. However, the filter cartridge is discarded and replaced after each use.
- **Powered-Air-Purifying.** In this type of respirator, a battery-powered blower is used to pass air through filters.

According to NIOSH, filtering facepiece respirators are further classified according to their filtration percentage and oil resistance, as shown in Table 3.³² However, in Europe,

respirators must meet the European Standard which has three classes of disposable particulate respirators termed as FFP1, FFP2, and FFP3.

Table 3. NIOSH-Approved Filtering Facepiece Respirator Classifications for Nonpowered Air-Purifying Respirators

types of filtering facepiece	definition
N	non-oil-resistant
N95	filters at least 95% of airborne particulates and aerosols as small as 300 nm
N99	filters at least 99% of airborne particulates and aerosols as small as 300 nm
N100	filters at least 99.97% of airborne particulates and aerosols as small as 300 nm
R	somewhat oil-resistant
R95	filters at least 95% of airborne particulates and aerosols, service life: 8 h
R99	filters at least 99% of airborne particulates and aerosols
R100	filters at least 99.97% of airborne particulates and aerosols
P	strongly oil-resistant/oil-proof
P95	filters at least 95% of airborne particulates and aerosols, service life: 40 h
P99	filters at least 99% of airborne particulates and aerosols
P100	filters at least 99.97% of airborne particulates and aerosols

Both medical and N95 masks offer protection against the SARS-CoV-2 virus.^{53,67} Medical masks protect users from large respiratory droplets, whereas N95 respirators specifically protect users from small airborne particles, including aerosols.^{40,67} Surgical N95 respirators are a subset of N95 respirators used by healthcare professionals who require protection against airborne as well as fluid hazards. These respirators are both approved by

NIOSH and authorized by the FDA. Surgical N95 respirators are not required for caring for patients with COVID-19.⁶⁸

Figure 3 depicts the types of masks and respirators available in markets approved by U.S. and European standards.

2.3. Role of N95 Respirator against the Spreading of SARS-CoV-2. N95 respirators can effectively filter biological airborne particles such as viruses and bacteria⁶⁹ and can thus reduce the risk of the contamination in the surrounding area when a person coughs or sneezes. They can filter out at least 95% of particles as small as 300 nm from the air without leaking these particles around the mask. Therefore, SARS-CoV-2 transmission due to particles smaller than the 5000 nm droplets produced during talking, sneezing, and coughing can easily be filtered out by N95 respirators.^{70–72} Furthermore, individual SARS-CoV-2 viruses are a few orders of magnitude smaller than 300 nm, primarily travel by Brownian motion, and are effectively captured within the N95 filter via mechanical and electrostatic forces.⁷³ For this type of virus filtration, a tight-fitting N95 respirator offers advantages over a loose-fitting surgical mask by eliminating leakage around the mask when the user inhales.⁷⁴ This characteristic indicates that almost all of the air is directed through the filter media. Therefore, seal checks are an essential factor when health workers are using this respirator against COVID-19 infection. According to United States regulations, workers must pass a quantitative fit test to confirm a proper seal before using a respirator in the workplace, such as in hospitals. A user's seal check is required each time when the respirator is worn by the wearer after the fit test. This seal check can be done by exhaling gently after the mask was donned, and paths for air to exit the face piece were blocked. If the facepiece is slightly pressurized, then it is considered to be satisfactorily sealed. When a healthcare personnel is exposed to aerosolized pathogens causing acute respiratory infections, an air-purifying



Figure 3. Different types of available facial masks or respirators. Most common types of respirators: *Cloth mask*: Simplest option used by many people with minimum protection against microscopic particles, but capable of filtering large dust-type particles. *Surgical mask*: Usually, one side is light blue, and the other side remains white; mostly used by healthcare providers. Additionally, it is loosely fitted over the mouth and nose, is fluid-resistant, and mostly prevents entry by large droplets. Respirators following U.S. standards: *N95*: These respirators filter out at least 95% of airborne particulates and aerosols as small as 300 nm. *N100*: These respirators filter at least 99.97% of airborne particulates and aerosols as small as 300 nm. *P100*: These respirators remove at least 99.97% of airborne particulates and aerosols. *R95*: These respirators filter (at least 95%) oil- and non-oil-based particles with increased durability. Respirators following European standards: *FFP1*: Filters out 80% of 300 nm particles. *FFP2*: A tightly fitted device reduces exposure to airborne particles with a filtering efficiency of greater than or equal to 94%. *FFP3*: Similar to the N100-type respirator with a slightly lower filtration efficiency.

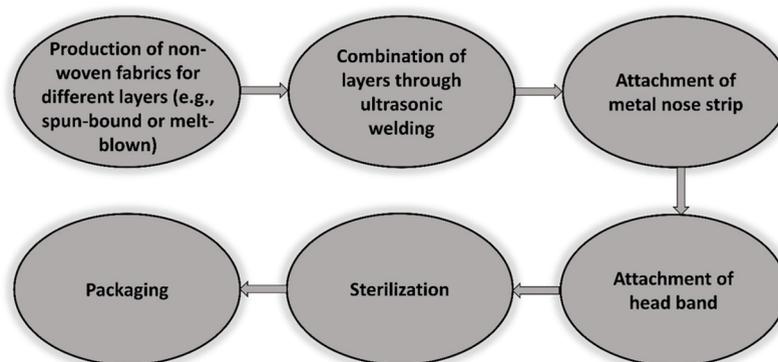


Figure 4. Basic process steps involved in the production of disposable medical N95 respirators. Different nonwoven layers are produced first and laminated together by using ultrasonic welding. Then, the respirator is assembled followed by the attachment of metal nose strips and a head band. Sterilization using different methods is performed before packaging.

respirator with cartridges can be more useful. However, no fit testing or seal check is required with the surgical face masks.

During pandemic or emergency situations, health authorities often refer N95 respirator (United States NIOSH-42CFR84) and FFP2 (Europe EN 149-2001)-type masks in the workplaces.⁷⁵ However, due to an unusually high demand for these respirators, availability was limited, and many organizations were not able to obtain standard respirators. Therefore, alternative respirator options have been considered for some healthcare tasks. Based on a comparison, it is reasonable to consider that KN95 (China), AS/NZ P2 (Australia/New Zealand), KF94 (Korea), and DS/DL2 (Japan) are equivalent to US NIOSH N95 and European FFP2 standards⁷⁶ for protecting workers from this specific virus.

3. N95 RESPIRATOR: MATERIALS AND PRODUCTION PROCESS

N95 respirators are specialized masks available for both industrial and medical applications. 3M was the first manufacturing company which developed N95 masks for industrial purposes. Here, we will concentrate on medical N95 respirators, which are single-use products under class II that have been approved by both the FDA and NIOSH. N95 respirators come with different shapes, so healthcare workers can find a model that best fits their faces. Some N95s feature exhalation valves, which assist the user in breathing more easily and reduce heat build-up. However, an N95 respirator with exhalation valves should not be used when sterile conditions are needed, as the valves allow unfiltered, exhaled air to escape into the sterile field.⁶⁸

The automated production of the N95 provides larger production and greater consistency in quality within a short period of time. During the coronavirus pandemic, due to the high need for essential PPE, such as medical and surgical masks, to protect frontline workers, an automated process has played a key role in fulfilling this requirement.

3.1. Materials Required for a Medical N95 Respirator.

Multiple layers of nonwoven material are typically used to design a medical N95 respirator. Normally, four layers of nonwoven materials are laminated together. The two outward layers, with a density between 20 and 50 g/m², serve as a waterproof barrier that diminishes transmission by taking in any liquids expelled by the patient while talking, coughing, or sneezing. The mask consists of a shell and a cover web and is commonly prepared with polypropylene or polyester. Another layer that remains in

contact with the user's face absorbs the moisture produced during exhalation.⁷⁷ This layer is termed nose foam and is typically made from polypropylene or polyurethane. The outward protective layers of fabric are usually manufactured by a process named spun bonding.⁷⁸ In spun bonding, molten threads of a thermoplastic polymer blow through the nozzles (size range: 15 000–35 000 nm) to layer the threads on a conveyor belt. As the conveyor belt continues, the fibers bond into the cloth via thermal, chemical, and mechanical treatments.⁷⁸ In the middle of two spun bonded outward layers, a prefiltration layer (density 250 g/m²) and a filtration layer are present. The prefiltration layer is made of a nonwoven material that is needle-punched to enhance its cohesiveness.⁷⁹ Barbed needles repeatedly run through the fabric to hook the fibers together, and the layer then undergoes a hot calendaring process. Heated rollers under high pressure are used to bond the thermoplastic fibers thermally, resulting in a thicker and stiffer layer. This layer can be modeled to give any stable shape to the masks.

Notably, the filtration layer of the mask comprises a high-efficiency melt-blown nonwoven electret material named polypropylene (PP) which determines the filtration efficiency of the respirator. During the melt-blowing process, the finer fibers (measuring less than a micrometer) are brought out onto a conveyor through multiple nozzles using air. The material is made by the self-soldering of the threads as they cool down. The random orientation of the fibers on a conveyor, combined with the density and fine fiber size, makes it feasible to filter away the smallest number of molecules with high efficiency. Sometimes, melt-blown material is also thermally bonded to add strength and abrasion resistance at the expense of material characteristics.⁷³ The material is then charged through corona discharge and/or triboelectric means into quasipermanent dipoles called electrets to improve filtration efficiency while maintaining high air permeability.^{80,81} This treatment allows an electrostatic adsorption of aerosolized particles via electrostatic attraction without affecting the mass or density of the mask structure. For this reason, the material is efficient for filtering viruses and other pathogens in medical contexts. Metal wires such as aluminum wires are used for nose clips. A nose clip helps to accommodate the mask to the user's nose and improves sealing. NIOSH does not approve N95 that have ear loops; however, some products are available with ear loops/straps made up of a thermoplastic elastomer that are likely to be counterfeit. FDA has authorized

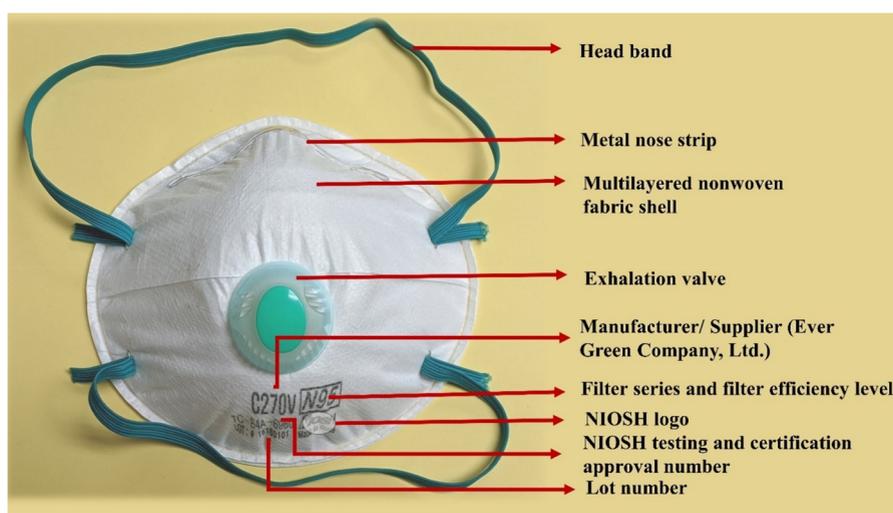


Figure 5. Illustrations of the basic components and markings for identifying approved NIOSH N95 respirators (exterior view).

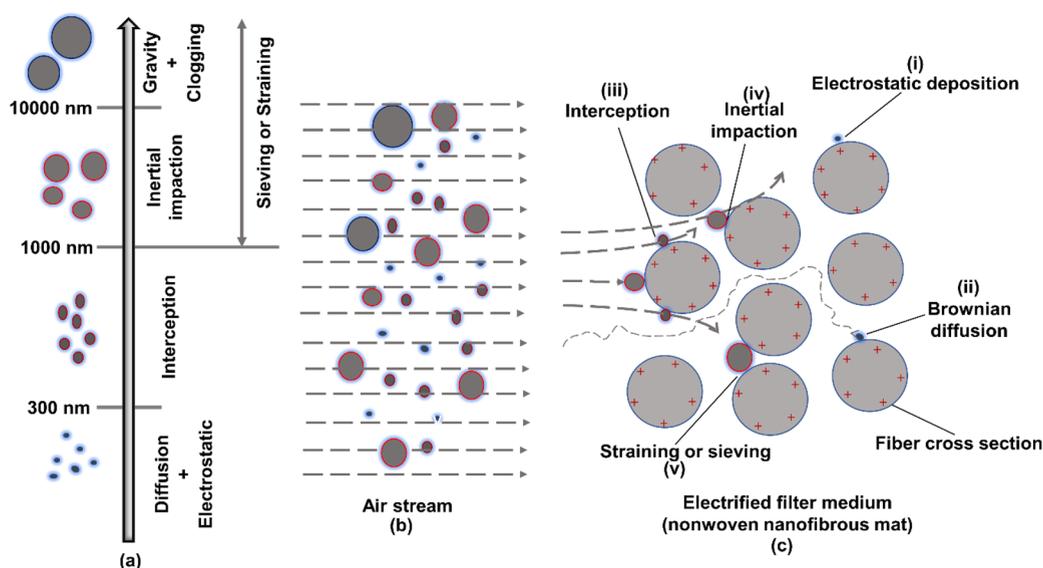


Figure 6. Schematic illustration of the mechanism of air filtration in a nonwoven fibrous mat. (a) Different filtering effects based on the particle size. (b) Air stream carrying particles of different sizes. (c) Filtration in electrified filter medium by (i) electrostatic deposition, (ii) Brownian diffusion, (iii) interception, (iv) inertial impaction, and (v) straining or sieving.

some KN95 with ear loops for emergency use during this pandemic.

3.2. General Steps for Assembling N95 Medical Respirators. The production of disposable medical N95 respirators is shown in Figure 4. Single-use N95 cup-shaped respirator production includes the following basic steps:

- (i) *Combination of Multiple Nonwoven Layers.* Multilayer fabric is created by stacking the four layers of nonwoven materials together, which are passed through an ultrasonic welding machine.
- (ii) *Attachment of Nose Strip.* The machine stitches the flat metal wire onto the 3-layer fabric.
- (iii) *Attachment of Head Band.* The head band is attached using ultrasonic welding or an adhesive applied by a thermal press.
- (iv) *Sterilization.* Medical-grade masks are sterilized using ethylene oxide to inactivate the microbial contamination. As ethylene oxide is toxic and flammable, the treated

masks must be left to stand for 7 days until the ethylene oxide level dissipates.

- (v) *Packaging.* The completed masks are packaged for distribution.

3.3. Identification of NIOSH-Approved Respirators. A fully prepared, ready-to-deliver NIOSH-approved respirator should have some general components and markings applied for identification, as shown in Figure 5. In response to CDC and NIOSH standards, N95 respirators must possess the following printed information on the respirator itself:⁸²

- a registered trademark, an easily understood abbreviation of the approval holder's or manufacturer's name as recognized by NIOSH, or, if applicable, a private-label brand name (e.g., CV270 V);
- NIOSH name in block letters or the NIOSH logo;
- NIOSH testing and certification approval number (e.g., TC-84A-6960);

- NIOSH filter series alphanumeric rating followed by filter efficiency level (e.g., N95); and
- (also recommended, but not required) the lot number and/or date of manufacture.

4. AIR FILTRATION MECHANISM OF THE N95 MASK

The mechanical filtration efficiency of the N95 mask depends on the structure of the middle layer, which is made of polypropylene. This layer is a nonwoven fibrous filter that is connected together by entangling its underlying structures mechanically, thermally, or chemically.³⁴ The fibers are nonuniform in size and randomly oriented mostly perpendicular to the aerosol flow. To augment the filtering efficiency by 10–20 times, the middle layer is embedded with an electrostatic charge.⁸³ The electrostatic collection forces improve the collection of very small particles; however, as electrostatically charged fibers in an FFR become load, either the fibers are coated or the electrostatic forces are masked, and mechanical filtration becomes the primary mechanism of particle collection. The number of particles collected by the fiber relative to the number of particles in the volume of air geometrically swept out by the fiber is presented by a ratio named the single-fiber efficiency (E_{Σ}). It is related to the filter penetration (P) which is mathematically expressed as^{34,84}

$$P = e^{-4\alpha E_{\Sigma} t / \pi(1-\alpha)d_f} \quad (1)$$

where t is the filter media thickness, d_f is the fiber diameter, and α is the filter solidity or the fraction of the solid material in a filter. The total single-fiber efficiency E_{Σ} includes contributions from different collection mechanisms and can be written as

$$E_{\Sigma} \approx E_D + E_R + E_{DR} + E_I + E_E + E_G \quad (2)$$

where E_D , E_R , E_{DR} , E_I , E_G , and E_E represent the collection efficiencies due to diffusion, interception, the interception of the diffusing particles, inertial impaction, the electrostatic effect, and gravity, respectively.^{34,85} Hence, different filtration mechanisms have been considered for fibrous membrane filters. The mechanisms due to Brownian diffusion, interception, inertial impaction, straining or sieving, and gravity are mechanical capture mechanisms, whereas the electrostatic capture mechanism plays a dominant role when the aerosols or the filter possess electrostatic charges. All of these mechanisms are depicted in Figure 6.

4.1. Interception Effect. If the particles of finite size follow the flow line of the air flow streamlines and never deviate from it, the interception effect happens.^{34,85} Interception occurs when the aerosol particle center comes within one particle radius of the fiber surface and meets the surface of the fibrous filter materials under the effect of van der Waals forces (Figure 6c,iii).⁸⁶ Interception plays a vital role in nanoparticle filtration, especially when the fiber diameter is small. The air flow around the fiber and the particle size determine the single-fiber efficiency due to interception.³⁴ Interception is the main capture mechanism for particles in the range of 100–1000 nm, and filtration efficiency by interception increases with the increasing particle size.⁸⁵

4.2. Inertial Deposition or Impaction. The extremely complex arrangement of the fibers makes the streamline of the airflow tortuous. When the particle inertia keeps it from following the unexpectedly changing streamlines near the fiber, inertial impaction occurs; thus, the particle hits the fiber and then impacts and deposits on the fiber membrane (Figure 6c,iv).

Usually, larger particles with greater inertia have a higher filtration efficiency. Hence, this mechanism becomes the leading capture mechanism when the particle size exceeds 1000 nm, especially in the case of higher gas flow velocity.^{34,85,87} The single-fiber efficiency is computed based on the value of the Stokes number and spreads out in rather wide ranges at small Stokes numbers.⁸⁸ The accurate calculation of the efficiency at small Stokes numbers is still challenging because of the difficulty in distinguishing contributions from different filtration mechanisms within this range. It is assumed that when the Stokes number is high, the particle is moving almost in a straight line with its initial velocity, and the particle trajectory deviates slightly from the air streamline when the Stokes number is small.³⁴

4.3. Brownian Diffusion. Aerosol particles with sizes below 100 nm deviate from the original trajectory under the action of random Brownian motion and then hit the fibers, finally leading to deposition around the fiber surfaces of the filtration membranes (Figure 6c,ii).^{34,85} Brownian diffusion can be the dominant mechanism for nanoparticle filtration. Particles smaller than 300 nm exhibit significant Brownian movement, thus resulting in diffusion and deposition in the neighborhood of the fiber surfaces.⁸⁵ The single-fiber efficiency due to diffusion is a function of a dimensionless parameter, the Peclet number Pe , which represents the relative importance of convection and diffusion and is defined as

$$Pe = \frac{d_f U_0}{D} \quad (3)$$

$$D = \frac{kTC_c}{3\pi\mu d_p} \quad (4)$$

Here, U_0 is the filtration velocity, μ is the air dynamic viscosity, D is the diffusion coefficient, k is the Boltzmann constant, T is the absolute temperature, d_p is the particle diameter, and C_c is the slip correction factor.³⁴

4.4. Electrostatic Effect. The track of particles will be changed accordingly; when particles and/or fibers possess electrostatic charges or when the filter is subjected to an external electrical field, particles are attracted to deposit onto the fiber surfaces due to electrostatic interaction, i.e., Coulombic interaction and polarization forces (Figure 6c,i).^{85,89} The charged particles attract the oppositely charged fibers by Coulombic forces. A charged fiber can also induce a dipole or charge separation in a neutral particle by generating a nonuniform electrical field.³⁴ Equally, a charged particle can also induce the surface of a neutral fiber at close range. The resulting dielectric forces cause an attraction between the particle and fiber; however, these forces are weaker than the Coulombic forces. The electrostatic mechanism depends on particle size through mobility and charge distribution and plays key role when the particle size is below 100 nm.³⁴ Electrostatic interaction is a dominating mechanism in the case of air particle separation by the N95 mask.^{7,90,91} The greater the amount of charge on the mask fibers is, the higher the filtration efficiency. Electrostatic forces can substantially increase the air particle collection efficiency; therefore, the application of electrostatic forces is widely used.

4.5. Sieving or Straining. Straining or sieving occurs when the opening between the filter fibers is smaller than the diameter of the particle (Figure 6c,v). When the particle size is large enough (>1000 nm) to be entrapped between adjoining filter

media fibers, straining becomes dominant. This mechanism also largely depends on the fiber diameter and density of the filter medium.

4.6. Gravity Effect. Since aerosol particles are very small, the effect of the gravitational force seems to be minimal among the above-mentioned effects, and sedimentation can be thoroughly ignored when the particles are smaller than 500 nm.^{85,89} Gravitational settling may lead particles to be collected in the filter because of their deviation from the streamlines.

The filtration mechanism of solid aerosols is quite different from that of liquid aerosols.⁹² In the case of solid aerosols, the pressure drop across the filter increases with the deposited mass of aerosols. First, aerosol particles are deposited on the surface of individual fibers in the filter bed followed by accumulation on the fiber surface forming a cake on the surface of the filter.^{93,94} When a complete cake forms, sieving becomes the dominant filtration mechanism; hence, the filtration changes from “depth filtration” to “surface filtration”. However, for liquid aerosols, the filtration efficiency first declines continuously and then finally reaches an equilibrium value. The ability of liquid particles to coalesce and flow creates this difference between their deposition mechanisms.⁹⁵ Their loading behavior depends on the occurrence of internal relocation, drainage, re-entrainment, and so on, while solid particle loading creates a permanent structure that does not change easily until, ultimately, a cake is formed on the filter surface.⁹²

5. PERFORMANCE EVALUATION OF THE N95 FILTERING DEVICE

Most NIOSH-certified N95 FFRs offer more than 95% filtration efficiency for a wide range of particle sizes (4–100 000 nm). They deliver almost 100% protection from particles ranging from large droplets (>100 000 nm) to inhalable droplets (10–100 000 nm) and to nuclear aerosols (<10 000 nm).^{22,96,97} In addition, these FFRs provide a filtration performance of greater than 95% against particulates between 4 and 400 nm.^{91,98} FFRs show a most penetrating particle size (MPPS) of 40–100 nm when constructed from electret filter material.^{98,99} However, when electrostatic charges are removed by using solvents such as isopropanol, penetration increases noticeably, and the MPPS increases to 200–400 nm. This higher range is anticipated for filters relying exclusively on mechanical collection mechanisms (interception, impaction, and diffusion).⁹⁸

Many researchers have evaluated the performance of the selected filtering device by using both inorganic and biological particles.^{69,91,98,100} Sometimes both types of particles are targeted along with a modified testing process to win the confidence of healthcare professionals in the real world. Moreover, the variable flow rate of these particles is considered equally important for evaluating the performance of any respirator or mask under testing. Generally, the particulates present in air vary widely in size and shape with different physicochemical behaviors. Particle penetration is contingent on the face velocity based on the flow rate and available surface area, aerosol particle size, air viscosity, temperature, and several filter parameters, including the thickness, fiber diameter, and fiber packing density.⁸⁸ The most important particle size in a test condition is the MPPS, which generally occurs between 50 and 500 nm depending on the filter properties and face velocity (Table 4).⁸⁴ The following sections summarize the literature on N95 respirator performance evaluations based on the types of aerosol particles examined, the nature of the air flow, and other potential factors that might influence their performance.

5.1. Performance against Inorganic Particles. The conventional method of performance evaluation is used to certify N-series respirators under NIOSH Title 42 Code of Federal Regulations Part 84.¹⁰¹ In this test, sodium chloride (NaCl) particles are employed as the challenge aerosol. NIOSH only varies the flow rate during certification testing depending on the configuration of the nonpowered air-purifying respirator. Balazy et al. described a manikin-based performance evaluation setup, as depicted in Figure 7.⁹⁰ A manikin-based protocol is used to evaluate the penetration performance at different inhalation flow rates, most commonly at 30 and 85 L/min as a light workload and heavy workload, respectively. The aerosol concentration is measured outside and inside the facepiece using a wide-range particle spectrometer (WPS) and is plotted against the particle size. The targeted particle sizes ranged from 10 to 600 nm. However, for many standard certification tests, particles of ~300 nm are used, because they are assumed to be the most penetrating size. The manikin is equipped with a probe to sample the aerosols inside the facepiece.⁹⁰

In general, N95 respirators have higher filtration efficiencies, with at least 95% efficiency for NaCl particles with sizes of 100–300 nm, which reaches 99.5% or higher at approximately 750 nm when tested at a certification flow rate of 85 L/min.²⁶ Qian et al. found almost 100% removal efficiency for most environmental particles, except submicron particles with sizes of less than 750 nm.²⁶ The maximum penetrated mass fraction for particles smaller than 750 nm is 1.8% in the absence of face leakage. The respirators even show a better performance at low or medium workload conditions when the flow rate is less than 85 L/min. However, N95 respirators show higher penetrations of engineered nanoparticles (1–100 nm), such as titanium dioxide (TiO₂), carbon nanotubes (CNTs), and fullerene, compared to those measured for NaCl aerosols. In a study performed by Zhou et al., the penetration of these engineered nanoparticle aerosols exceeded 5% and was often greater than 5% near the MPPS (90–150 nm) (Figure 8).⁹⁹ This MPPS range is relatively higher than the MPPS range (40–100 nm) of NIOSH-certified N95 FFRs tested for NaCl particles. A possible reason for the higher maximum penetrations and shift in the MPPS to larger particle sizes observed for these engineered nanoparticles may be related to electrostatic collection processes. For respirators without electrostatic force, which are treated with isopropanol to remove electric charges, the penetration of NaCl and engineered nanoparticles increased significantly with the increase in MPPS to 150 nm for both types of aerosols.

The NIOSH certification requirements need a filter performance evaluation against harmful aerosols during worst-case or severe conditions.⁸⁸ Because the workplace is in a less severe environment compared to the experimental conditions during certification, the filters are supposed to perform better than their certification level. Certification tests use photometers to measure the light scattering of the challenge aerosol, providing an indication of the aerosol mass penetration.¹⁰¹ However, Rengasamy et al. suggested that the NIOSH respirator certification protocol using the photometric method might not be a more challenging aerosol test method.¹⁰² These researchers found several-fold less penetration for penetrations using the NIOSH test method than the penetrations obtained by an ultrafine condensation particle counter for NaCl aerosols as well as for room particles. The particle counting measurement offered a more difficult challenge than the photometric method, which lacks sensitivity for particles <100 nm. Different types of particulates are used to challenge the filters to verify their

Table 4. Performance Evaluation Overview of N95 Masks in Terms of Nanoparticle Filtration

testing method	testing specification	particle materials (size range)	filter media specification	filtration efficiency	remarks	year and ref
dynamic aerosol size spectrometry	air velocity, 8 cm/s, corresponding to breathing at 85 L/min, and 300 cm/s, corresponding to violent sneezing and coughing; relative humidity, 22%; temperature, 25 °C; particles were neutralized by a 10 mCi ⁸⁵ Kr electrostatic neutralizer	inert particles and TB surrogate bacteria at an aerodynamic diameter of 800 nm	N95 respirator	reaerosolization percentage of 0.025% for particles less than 1000 nm, 0.1% for 3000 nm, and 6% for 5000 nm	possibilities of reaerosolization when the wearer sneezes or coughs at exhalation; larger particles were more prone to reaerosolization; significant reaerosolization of particles smaller than 1000 nm	1997 ²²
particle-size spectrometers	flow rate, 85 L/min; particles were neutralized by Kr 85	polydisperse NaCl (<700 nm); polystyrene latex (PSL) (600–5100 nm); two non-pathogenic, rod-shaped bacteria (<i>Bacillus subtilis</i> and <i>Bacillus megaterium</i>) (700–800 nm in diameter and 2000–3000 nm in length), which were close to the size of <i>Mycobacterium tuberculosis</i>	one cone-shaped N95 respirator and two flat respirators	95% efficiency for NaCl and PSL particles for sizes 100–300 nm, reaching 99.5% or higher at approximately 750 nm; for bacteria, the filtration efficiency is also 99.5% or higher	N95 respirators provided excellent protection against airborne particles when there was a good face seal	1998 ²⁶
monodisperse particles by DMA, CNC for detection	flow rate, 85 L/min; particles were neutralized; filter media were made of electret	NaCl and DOP (30–400 nm)	three models of N95 FFRs	95–90% at MPPS of 50–100 nm	tested N99, R95, and P100 filter media with NaCl and DOP	2000 ⁹⁸
electrical low-pressure impactor used to measure particle concentration	flow rates, 30 and 85 L/min; particles were neutralized by Kr 85; temperature, 23 ± 1 °C; relative humidity, 42 ± 9%	particles with sizes ranging from 40 to 1300 nm	N95 respirator, R95 respirator, dust-mist respirator	reduction in ultrafine particle penetration up to 3000-fold	dramatic increase in aerosol filtration efficiency observed due to continuous unipolar ion emission by corona-ionizing air purifiers	2005 ¹³³
wide-range particle spectrometer (polydisperse particles, size distributions)	flow rate, 30 and 85 L/min; particles were neutralized by Kr 85; filter media were electret	NaCl (10–600 nm); MS2 virus in the particle size range from 10 to 80 nm	N95 half face piece respirators (composed of 3 polypropylene layers); <i>d_f</i> from 7 to 40 μm	94–99.9% (0.1–6% penetration)	MPPS, 30–70 nm for electret filter; penetration over 5% was also evident for some N95 filters	2006 ⁷
wide-range particle spectrometer (polydisperse particles, size distributions)	flow rate, 30 and 85 L/min; particles were neutralized by Kr 85; filter media were electret	MS2 virus (a nonharmful simulant of several pathogens) (10–80 nm)	Two models of N95 half face piece filtering respirators	94–99.5% (0.1–6% penetration)	N95 may not completely protect against small viruses	2006 ⁹⁰
various methods	cyclic flows from 40 to 430 L/min; particles were neutralized; filter media were charged and uncharged	inert particle and bacterial <i>B. globigii</i> spores and virus MS2 phage 20–3020 nm	N95 and P100 filtering facepieces and cartridges	efficiency, 95–99.995%	MPPS, 100–200 nm for the P100 filters and 50–100 nm for the N95 filters	2006 ¹³⁴
<i>in vivo</i> filtration test	25 °C and relative humidity was 70%	fluorescein-KCl solution was used to simulate viral aerosols	N95 respirators	filtration efficiency >97%	filtered out 97% of KCl solution but showed lower air and water vapor permeability	2006 ¹³⁵
polydisperse particles; long-DMA, nano-DMA, CPC, and APS together measuring the size distribution	flow rate, 30, 60, and 85 L/min; particles were neutralized; respirators dipped in IPA 5 min to remove charges	4.5–10 000 nm NaCl from atomizer	N95 and FFP1 respirators; <i>d_g</i> 10.8 cm; <i>d_p</i> 13 000 nm; <i>α</i> , 0.035	filtration efficiency, 81–100%	no rebound effect for particles down to 4.5 nm; penetration for 10–5000 nm increased when reducing electrostatic charge on the filters; error in SMPS due to 0 break time	2007 ¹³⁶
monodisperse particles by DMA, CPC for detection	flow rate, 85 L/min; particles were neutralized; filter media electret	20–400 nm NaCl	five models of N95 FFR	98.6–94.8% at MPPS of ~40 nm	results were compared with NIOSH certification method	2007 ¹³⁷
nano-DMA and UCPC for monodisperse Ag and NaCl, TSI 3160 for monodisperse NaCl	flow rate, 85 L/min; particles were neutralized; filter media electret	4–30 nm (Ag); 20–400 nm (NaCl)	N95 and P100 respirators	approximately 95–99.9999%	MPPS, 40–50 nm; respirators provided expected protection; penetration of 4 nm particles was a few orders of magnitude less than that of 30 nm particles	2008 ⁹¹
polydisperse particles, size distributions measured by wide-range particle spectrometer	flow rates, 30, 85, and 150 L/min; particles were neutralized by Kr 85; filter media were electret	20–500 nm (NaCl); 28 nm for MS2; various sizes for other viruses, NaCl, and three virus aerosols (MS2, T4, and <i>Bacillus subtilis</i> phage)	two models of N99 FFRs and one N95 FFR	penetration percentage 0.1–10%	at a high flow rate of 150 L/min, the penetration can increase significantly; MPPS, <100 nm for all aerosol challenges	2008 ¹³⁸

Table 4. continued

testing method	testing specification	particle materials (size range)	filter media specification	filtration efficiency	remarks	year and ref
electrical low-pressure impactor used to measure particle concentration	sampling flow rate, 10 L/min	NaCl particles representing bacterial and viral size ranges (aerodynamic size, 40–1300 nm)	N95 respirators	protection factor <10	may not achieve the expected protection level against bacteria and viruses; the exhalation valve does not affect the respiratory protection; the protection factor indicated that the Occupational Safety and Health Administration (OSHA) PF of 10 may overestimate the actual protection against bacteria and viruses	2008 ¹⁰⁰
polydisperse particles by APS detection	flow rates, 85, 270, and 360 L/min	NaCl and DOP (20–2900 nm)	two models each of N95 FFR and cartridges, P100 FFR and cartridges	N95, 99.3–91.2% at MPPS (50 nm); P100, 99.9996–99.95% at MPPS (50–200 nm)	Penetration increased under increased constant and cyclic flow conditions; the MPPS was relatively unaffected by flow	2009 ⁸⁸
photometric methods and an ultrafine condensation particle counter method (UCPC) (count-based)	flow rate, 85 L/min	polydisperse NaCl particle (20–1000 nm)	five models of N95 FFR	penetrations measured by UCPC were 2–6 times greater than the levels measured by the photometric method; for room air particles, it was 3–8 times	UCPC method showed 2–6 times greater penetration than the photometric method	2011 ¹⁰²
particles were measured using gelatin filters and an Andersen Cascade Impactor (ACI)	simulated cough (370 L/min peak flow) provided reverse airflow through the contaminated FFR; the particles were neutralized by Kr 85	bacteriophage MS2 as a surrogate for airborne pathogenic viruses	N95 FFR	small percentage (<0.21%) of viable virus was re-aerosolized	negligible risks of exposure due to re-aerosolization associated with extended N95	2011 ¹¹⁸
particle size and concentration were determined by scanning mobility particle sizer with an ultrafine condensation particle counter	flow rate, 8–30 L/min; particles were neutralized by Kr 85	NaCl polydisperse particles (20–400 nm)	N95 FFR		MPPS shifted from 45 to 150 nm for the charge removal filters, indicating that mechanical filters (MPPS, 45 nm) perform better against nanoparticles than electrostatic filters (MPPS, 150 nm) rated for the same filter efficiency; good fitting respirators provided better protection against nanoparticles	2012 ¹¹⁴
automated breathing and metabolic simulator (ABMS)-based test to evaluate the inhaled CO ₂ and O ₂ concentrations and breathing pressures for FFR and SM	minute ventilation, 0–160 L/min; O ₂ consumption, 0–7 L/min; CO ₂ production, 0–7 L/min; respiratory frequency, 0–100 breaths/min; tidal volume, 0–5 L; and humanlike breathing gas temperatures, 30–45 °C	evaluation of inhaled CO ₂ and O ₂ concentrations and breathing pressures	30 NIOSH-approved FFR models and 1 flat-fold SM model		inhaled gas composition changed for addition of SM with FFR; the orientations of the SM on the FFR have a significant effect on the inhaled breathing quality and breathing resistance	2013 ¹²⁷
electrostatic classifier (EC) containing a long differential mobility analyzer (DMA) and a condensation particle counter (CPC)	four cyclic flows with PIFs of 135, 210, 270, and 360 L/min were primarily chosen; a Kr 85 electrostatic neutralizer was used for charge neutralization	polydisperse NaCl, within the range from 10 to 205.4 nm	N95 FFR	6% penetration for high flow rate	constant flow provides MPPS penetrations (worst-case scenario) equal to or greater than the MPPS penetrations of the cyclic flow; for >2.30 L/min flow rate, increased MPPS penetration was observed for the constant flows rather than for the cyclic flow	2014 ¹⁰⁸
scanning mobility particle sizer (SMPS)	flow rate, 5–70 L/min	neutralized polydisperse sodium chloride aerosols (18–950 nm)	N95 respirator	low penetration (5% or less) at the highest flow rates; for pediatric use, penetration at the highest flow rates (15% to >50%)	intrinsic penetration in the submicron size range was high for pediatric use	2015 ¹³⁹
aerosol concentrations were measured with a scanning mobility particle sizer	flow rates, 30, 85, and 130 L/min; isopropanol was used to neutralize the filter charge	engineered nanoparticles TiO ₂ , CNT, and fullerene (1–100 nm)	two commercial N95 filtering facepiece respirators	NaCl aerosol penetration was less than 5%; engineered particles exceeded 5%	engineered particles show greater penetrating compared to NaCl; most penetrating particle sizes (MPPSs) shifted to a size range of 90–150 nm	2016 ⁹⁹
NIOSH NaCl method; particulate filtration efficiency (PFE) and bacterial	flow rate, 85 L/min; samples were preconditioned at 85 ± 5% relative humidity and 38 ± 2.5 °C for 2.5 ± 1	NaCl aerosol (NIOSH NaCl method); 100 nm size polystyrene latex particles (for PFE); 3000 nm size particles containing	six N95 FFR models, three surgical N95	efficiencies measured by the NIOSH NaCl method for N95 FFRs were from 98.15%	NIOSH NaCl method showed lower efficiency than the other methods; NIOSH NaCl method is able to identify poorly performing filtration devices;	2017 ¹⁴⁰

Table 4. continued

testing method	testing specification	particle materials (size range)	filter media specification	filtration efficiency	remarks	year and ref
terial filtration efficiency (BFE) methods, and viral filtration efficiency (VFE)	h prior to measuring filter penetration	<i>Staphylococcus aureus</i> bacteria (for BFE); 3000 nm size particles containing phIX 174 as the challenge virus and <i>Escherichia coli</i> as the host (for VFE)	FFR models, and three SM models	to 99.68% compared to 99.74–99.99% for PFE, 99.62–99.9% for BFE, and 99.8–99.9% for VFE methods	adding PFE, BFE, and VFE will not improve respirator certification status	
aerosol filtration test apparatus assembled at Microbac per modified ASTM F2101-14	flow rate, 28.3 L/min	influenza A virus, rhinovirus 14, <i>S. aureus</i> , paraffin oil and sodium chloride (surrogates for PM2.5)	N95 respiratory face mask with or without a valve and microventilator on aerosol filtration efficiency of a new	>99.7% efficiency for influenza A virus, rhinovirus 14, and <i>S. aureus</i> and >99.3% efficiency for paraffin oil and sodium chloride	effectiveness values of the different mask configurations were not different; the efficiencies of the masks at excluding smaller (i.e., rhinovirus and bacteriophage ΦX174) vs larger microbial agents (influenza virus, <i>S. aureus</i>) were not different	2018 ¹²⁵

filtration efficiency. For example, NaCl aerosols are used for N-series filters, whereas dioctyl phthalate (DOP) aerosols are used for R- and P-series filters. Both NaCl and DOP aerosols have count median diameters (CMDs) of 75 ± 20 and 185 ± 20 nm, respectively, and are charge-neutralized.^{88,103} However, Rengasamy et al. found that a monodispersed silver nanoparticle-based test system was more reliable for measuring the filtration efficiency of N95 respirators.⁹¹

5.2. Performance against Biological Particles. Balazy et al. evaluated the filter performance of certified N95 FFRs for both NaCl particles (10–600 nm) and the MS2 virus (10–80 nm), a nonharmful simulant of several pathogens.^{7,90} The results showed that the N95 masks failed to provide the expected protection level against small particles within a 10–80 nm range, especially at higher inhalation flow rates. For the virus sample, penetration exceeded the 5% threshold at the higher inhalation flow rate with a mean value of 5.6%, showing that the maximum penetration (~6%) occurred at a particle diameter of approximately 50 nm.⁷ The authors concluded that the certified N95 respirators may protect their wearers properly against particles measuring 300 nm and larger, but their performance may be below the threshold for particles in the nanosize range. For airborne bacteria, such as surrogates of *Mycobacterium tuberculosis* with an aerodynamic size of 800 nm or larger, the filtration efficiency of N95 respirators is reported to be 99.5% or higher when tested at a certification flow rate of 85 L/min.²⁶

In a separate study, determining the protection factors (PFs) provided by the N95 FFR against particles representing bacterial and viral size ranges (aerodynamic size: 40–1300 nm), Lee et al. inferred that N95 FFRs might not achieve the required protection level against bacteria and viruses.¹⁰⁰ Even the use of the exhalation valve on the N95 respirator did not affect respiratory protection; it appeared to be an appropriate alternative to reduce breathing resistance.

5.3. Performance at Different Air Flow Rates. In the NIOSH test, the filters are challenged at a constant flow rate of 85 L/min (for a single filter respirator) or at 42.5 L/min (for a double filter respirator). Additionally, the filters are usually loaded with a minimum of 200 mg of aerosols. The competency of the constant 85 L/min airflow used in the NIOSH test condition to imitate real field conditions has been the center of much dispute. The average exhaustive ventilation rates at different work intensities were found to be as high as 114 L/min,^{104–106} and at high workloads, the instantaneous peak flow rates are in the 300–400 L/min range.¹⁰⁷ These high ventilation rates and high peak flows are unlikely and occur for a short duration at exhaustive workloads; however, these upper limits are above the constant 85 L/min test flow maintained in the NIOSH certification test.⁸⁸

Bahloul et al. evaluated the penetration of particles (polydispersed NaCl), mostly in the ultrafine range (<100 nm), through N95 FFRs subjected to cyclic and constant flows, simulating breathing for medium to heavy workloads.¹⁰⁸ The constant flow provided MPPS penetrations (worst-case scenario) of equal to or greater than the MPPS penetrations of the cyclic flow and could better predict the results of the corresponding cyclic flow. For lower flow rates (42–170 L/min), there was no significant difference in the MPPS penetration between the constant and cyclic flows, whereas for >230 L/min, a significant increase in MPPS penetration was noted for the constant flows rather than for the cyclic flow.

Eshbaugh et al. investigated the effect of high-flow conditions, which may be encountered during heavy work, on aerosol

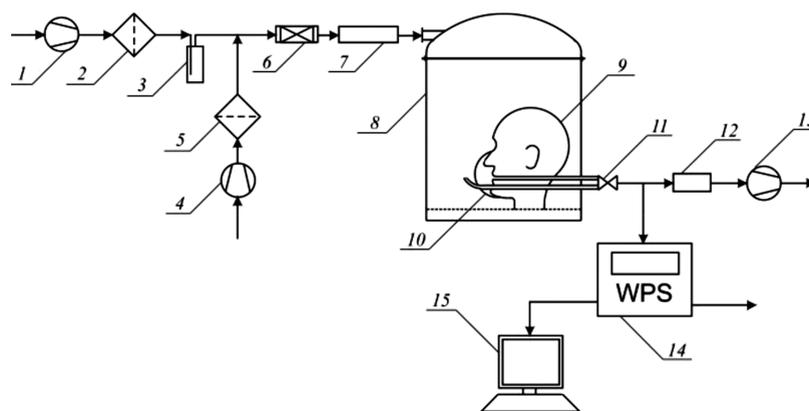


Figure 7. Schematic diagram of a manikin-based experimental setup to measure particle penetration through an N95 respirator. After being aspirated by a fan (1), the ambient air is purified in the filter (2) and then supplied to an aerosol generator (3) (a six-jet collision nebulizer). A pump (4) is used to dilute the generated aerosol by supplying clean air. The diluted aerosol is passed through a dryer (6) and an 85 Kr electrical charge equilibrators (7) and directed to the top part of the test chamber (8). The manikin (9) is placed inside the chamber, and the test respirator (10) is sealed on its face with a silicone sealant. A pump (13) is used to provide inhalation air flow to the manikin at a specific flow rate, which is controlled by a flow meter (12). The inside and outside aerosol sampling probes operating at 1 L/min were connected to a wide-range particle spectrometer (14) (WPS) and a personal computer (15). Adapted with permission from ref 90. Copyright 2005 Oxford University Press.

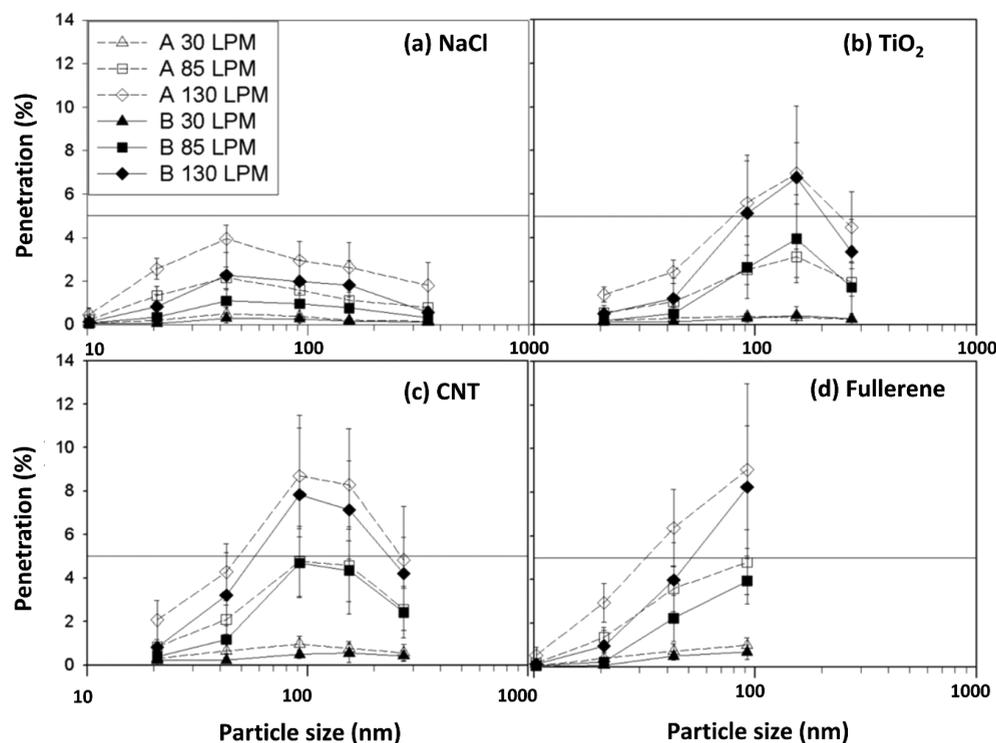


Figure 8. Penetration of NaCl (a), TiO₂ (b), CNTs (c), and fullerenes (d) in two types of N95 respirators A and B as a function of the particle diameter and flow rate (30, 85, and 130 L/min). The 30 L/min rate represents low to moderate workload. 85 L/min represents a moderate to high workload and is used for NIOSH respirator filter certification tests. 130 L/min represents inhalation at a very heavy workload. The MPPS shifted from approximately 40 nm for NaCl aerosols to approximately 90–150 nm for engineered nanoparticles (TiO₂, CNTs, and fullerene). Each data point shows the mean and standard deviation of 5 new units from respirator A (empty symbols) and respirator B (solid symbols). Adapted with permission from ref 99. Copyright 2016 Taiwan Association for Aerosol Research.

penetration and the connection between penetration at constant and cyclic flow conditions.⁸⁸ These researchers used both monodisperse aerosol and size-specific aerosol measurement equipment that allowed the count-based penetration measurement of the particles with a diameter range from 20 to 2900 nm. The penetration was found to increase at increased constant and cyclic flow conditions, which was consistent with previous

studies.^{25,26,90,109,110} The MPPS was approximately 50 nm for the N95 filters and was relatively unaffected by the flow.

5.4. Chances of Face Leakage. The current certification procedure estimates the filtration efficiency for filter media but not for face seal leaks, an important penetration pathway for aerosol particles.^{88,111} However, in the field, the N95 respirator wearer must pass a fit test before they can use the respirator in the workplace.^{112,113} The fit test measures total aerosol

penetration through the filter medium and the face seal leaks. Under actual breathing conditions, there are two possible penetration pathways for particles in the size range of 30–1000 nm: through (i) face seal leakage and (ii) the filter medium.^{114,115} Chen et al. studied face seal versus filter penetration for particles of 500–5000 nm with a breathing manikin under constant flow conditions and artificially created face seal leaks.^{116,117} Grinshpun et al. performed a test to differentiate between the two pathways clearly under actual breathing conditions.¹¹⁵ These researchers examined the contributions of these two pathways for the N95 FFR and surgical masks. All of these studies suggested that the penetration of the particles through the face seal surpassed the penetration through the filter medium. For the N95 respirator, the penetration was increased by an order of magnitude with an increase in particle size (e.g., approximately ~20-fold for 1000 nm). However, the surgical mask was not significantly affected by the particle size. Facial/body movement, breathing intensity, and facial dimension show pronounced effects on the relative contributions of the two penetration pathways.

5.5. Chances of Reaerosolization. On a different note, the supply of N95 filtering respirators may not be sufficient to match the demand during a pandemic. Hence, healthcare providers use the same respirators for multiple patient encounters. If the reaerosolization of virus particles occurs from contaminated respirators, then the mask may serve as a source of virus particles.¹¹⁸ The respirator of a healthcare provider may become contaminated with virus particles when in close interaction with an infected patient, and then, if he or she enters the room of a subsequent patient, the virus particles may reaerosolize due to the airflow (breathing, coughing, and sneezing) generated by the healthcare providers, causing a hazard to the surrounding area.¹¹⁸ Several studies reported no detection of reaerosolization from the N95 mask under normal working conditions.^{22,118–121} However, there is a potential chance of reaerosolization of already collected particles from the filter of the mask if (i) a respirator does not contain an exhalation valve, (ii) the wearer sneezes or coughs, and (iii) blowers or high-powered fans are used in the room.^{22,119–121} Qian et al. demonstrated the possibilities of reaerosolization when the wearer sneezes or coughs at exhalation air velocities exceeding 25 times the breathing velocity through respirators under heavy workload conditions.²² These researchers found that larger particles were more prone to reaerosolization, especially at relative humidity levels lower than 35%, and concluded that the reaerosolization of particles smaller than 1000 nm (average size of SARS-CoV-2 is 125 nm) is insignificant even under violent sneezing and coughing conditions. Fisher et al. examined the reaerosolization of virus particles from contaminated N95 respirators using bacteriophage MS2 as a surrogate for airborne pathogenic viruses in both droplet and droplet nuclei forms.¹¹⁸ The viruses loaded as droplets were less susceptible to reaerosolization than those applied as droplet nuclei, and the size distribution of the reaerosolized particles was larger than the loading aerosol. The researchers inferred that the risks of exposure due to reaerosolization associated with extended N95 use could be considered negligible for most respiratory viruses.¹¹⁸

5.6. Other Factors Affecting the Performance. In addition to the basic modes of performance evaluation, there are many other factors that are considered equally important for the selected mask or respirator for use in a real environment. Modifying the minor properties of the respirator or changing the environment could be very effective. For example, the efficiency

of the filters can be enhanced drastically (up to 200% for a particle diameter of ~75 nm) by increasing the action of the electrostatic effect between the particles and filter media.¹²² Particles with sizes as small as 30 nm have been collected from the air by Balazy et al. and Rengasamy et al., with a removal efficiency of greater than 90% under the dominant action of particle-fiber electrostatic interactions.^{7,90,91} The charge level on the filter media fibers may change with time and use; consequently, the efficiency of the filter (for particles <100 nm) also decreases significantly.³⁴ Applying an external electrical field to polarize the fiber to then facilitate the movement of a charged particle toward the fiber may overcome the problem. Alternatively, the polarization of particles in the air by the external field can also produce dielectrophoretic forces on them.³⁴

To improve breathing quality and reduce the accumulation of exhaled carbon dioxide (CO₂), heat, and humidity in the dead space of the respirator, an exhalation valve (EV) or a microventilator (microfan, MF) can be used to vent out the expired air.^{123–126} The use of a mask with an EV or MF reduces the fractional concentration of inspired CO₂ (FICO₂) levels comparably closer to baseline levels. However, the primary purpose of an EV or MF is to decrease breathing resistance during exhalation. This decrease has no impact on the respirators' ability to provide adequate respiratory protection. This type of design has been reported to enhance the comfort and experience of the mask wearer. Zhou et al. evaluated the relative contributions of a mask, valve, and microventilator to the aerosol filtration efficiency of N95 respirators and did not identify any significant differences in the effectiveness of the N95 mask by using these features that were primarily intended to enhance comfort.¹²⁵ A concern with using these additional parts is that there is a potential chance of contaminating the environment or sterile field in a protected room with the exhaled particles exiting the respirator through the valve.

Another possible option to improve the performance could be the use of a surgical mask (SM) cover over N95 filtering facepiece respirators (FFRs), which has become one strategy to avoid surface contamination of FFRs in this pandemic situation. Moreover, the placement of the SM on the FFR improves inhaled breathing gas concentrations compared with FFRs without SMs.¹²⁷ In addition, the placement of SMs over FFRs with exhalation valves (EVs) may prevent the EV from opening, regardless of the activity intensity.¹²⁷ Sinkule et al. investigated the breathing air quality and breathing resistance when using FFRs with SMs (FFR+SM) and without SMs.¹²⁷ The compositions of inhaled gas in FFR+SM and FFR-only were significantly different at lower energy expenditure levels. Compared with FFRs without an SM, higher average inhaled CO₂ was observed in FFRs with SMs. However, the investigation suggested that the SM–FFR combination would produce clinically small changes in inhaled breathing gases and breathing pressures, resulting in a minimal effect on physical work performance.

Under the current global shortage of N95 respirators, healthcare workers need to reuse their N95 masks.¹²⁸ Using soap water or any medical-grade alcohol to disinfect the respirators significantly decreases the filtration efficiency of these masks (54% and 67%, respectively).¹²⁹ Juang et al. proposed a method to clean and reuse N95 masks at almost no cost but while retaining a filtering efficiency of 92.4–98.5%.⁸³ These researchers proposed reusing the N95 masks every 3–4 day of rotation, by heating for 60 min and steaming or boiling for

5 min followed by air-drying. However, if the inner surface of the mask is made with paper or tissue, the mask may lose strength during washing. Moreover, applying multiple disinfection processes to respirators may cause them to degrade significantly and fail the fit test. Very recently, Price et al. compared two promising disinfection methods for N95 facial masks: (i) dry heat [hot air (75 °C, 30 min)] and (ii) ultraviolet germicidal irradiation (UVGI; 254 nm, 8 W, 30 min). The N95 masks treated with hot air over 5 cycles did not show degraded fitting, while UVGI-treated N95 masks were significantly degraded in fit when the treatment was applied over 10 cycles and did not pass quantitative fit testing.¹³⁰ In another recent study, Liao et al. found that heat (≤ 85 °C) under humidity ($\leq 100\%$ relative humidity, RH) was the most promising, nondestructive method for the preservation of the filtration properties in melt-blown fabrics as well as N95-grade respirators.¹³¹ Even 50 cycles of treatment at 85 °C and 30% RH could preserve the filtration performance without a significant change in efficiency. The study revealed a negative impact of using liquids, such as alcohol solutions, chlorine-based solutions, or soaps, to clean the respirator because this treatment may reduce the static charge that is crucial for the FFR to meet the N95 standard. Another report claimed that disinfection by using ozone gas also showed excellent results for up to 72 disinfection cycles without a detectable degradation or loss of filtration efficiency.¹³² The details of their reusability will be discussed in the next section of this Review.

6. STABILITY, DURABILITY, AND REUSABILITY

Based on manufacturer recommendations, N95 masks are designed for single use. However, the COVID-19 pandemic has led to a significant shortage of N95 respirators among healthcare providers.¹⁴¹ Formally, the CDC and NIOSH do not recommend the decontamination and reuse of N95 respirators, but in a time of such scarcity, some strategies have been adapted based on individual clinical judgment and the available resources.¹⁴² Earlier in at 2020, the CDC updated the guidelines on N95 usage to help healthcare professionals in the moment of crisis.^{143,144}

- (i) Masks that passed the expiration date of their shelf life can be worn outside the operating room after ensuring proper sealing.
- (ii) Respirators with similar foreign standards, such as China's GB 2626-2006 and GB 2626-2019 standards and European EN 149-2001 standards, have been approved for use.
- (iii) Limited (5 times, recommended by the CDC) reuse of N95 masks for multiple patients while removing it between encounters.
- (iv) Prioritizing N95 masks for activities most at risk for infection, including aerosol-generating medical procedures.
- (v) Administrative controls to protect frontline workers include shortening the stay of medically stable COVID-19 patients in the hospital and the suspension of fit testing for masks. If there are no N95 masks left, then keeping healthcare workers at risk of severe illness should be kept away from coronavirus patients and workers who have already received virus care.

The CDC also recommends extending the use of N95 masks during this pandemic. The extended use of the N95 mask allows it to be worn repeatedly while visiting several consecutive

COVID-19 patients without removing it in between encounters. The prolonged use of N95 masks can be safe for up to 8 h. To save the masks from soiling, the current guidelines suggest wearing a face shield over the N95 masks.¹⁴³

A recent study suggested that coronaviruses lose the greater part of their viability after 72 h on plastic surfaces.⁵⁴ Therefore, it can be assumed that, over time, SARS-CoV-2 becomes inactive on the surface of the N95 respirator mask. For the safe and frequent reuse of N95 respirators without compromising their filtering efficiency, the CDC has noted a mask rotation strategy and decontamination after treatment with chemicals, radiation, or heat.¹⁴⁵ The denaturation of proteins (using heat or alcohols), disruption of DNA/RNA (by oxidizers, peroxides, and UV), and cellular disruption (by chlorides, aldehydes, or phenolics) are usually performed through the disinfection or sterilization of bacteria and viruses. For SARS-CoV-2 inactivation, these sterilization methods have not been exploited frequently, but some papers show relatively high-throughput results for the reuse of respirators. A mask can be reused approximately 5 times if there is minimal to no viral contamination on the surface. The following attempts can be made to reuse an N95 mask, ensuring careful evaluation by world-renowned organizations.

6.1. Rotation of Masks. Mask rotation is applicable only for cases when the user has a set of N95 masks, at least 5, per CDC. Rotation should be performed each day, allowing the masks to dry for more than 72 h so that the virus is no longer viable. Appropriate mask storage is required, either by hanging the respirators to dry or preserving them in a clean, breathable container such as a paper bag between uses, ensuring that the masks are not touching each other.⁸³ Additionally, a user seal check is recommended before each use. Proper donning/doffing is another important factor to prevent the mask from soiling inside or outside of the masks. When a mask is contaminated from aerosol-generating procedures or body fluids, the CDC recommends discarding it.

6.2. Reprocessing (Sterilization). N95 masks can be reprocessed using the following general recommended principles:

- (i) The method must adequately deactivate the viral load on the mask.
- (ii) The mask cannot be soiled by body fluids such as sweat and/or oral droplets (dirt, salts, or chemicals/aerosol particles).
- (iii) The efficiency of the masks, such as their adsorption, filtration capacity, and electrostatic ability, must be preserved.
- (iv) The fit of the masks should not be compromised.

6.2.1. Heat Treatment. Heat treatment (temperature with/without moisture) was effective as a sterilization process for viruses such as SARS-CoVs. Commonly, there are two pathways to apply this heat.

According to the CDC, treating with moist heat (heating at 60–70 °C and 80–85% relative humidity for at least 60 min) is one of the most promising methods, but it is highly dependent on the temperature, humidity, local environment, and exposure time to inactivate viral particles.¹⁴⁶ Additionally, this method affects the filtration efficiency of the masks. However, recent research reported slight changes in the filtration properties after 20 cycles of heat treatment in a humid environment.¹³¹ The fit of the respirators does not appear to be affected.¹⁴⁷

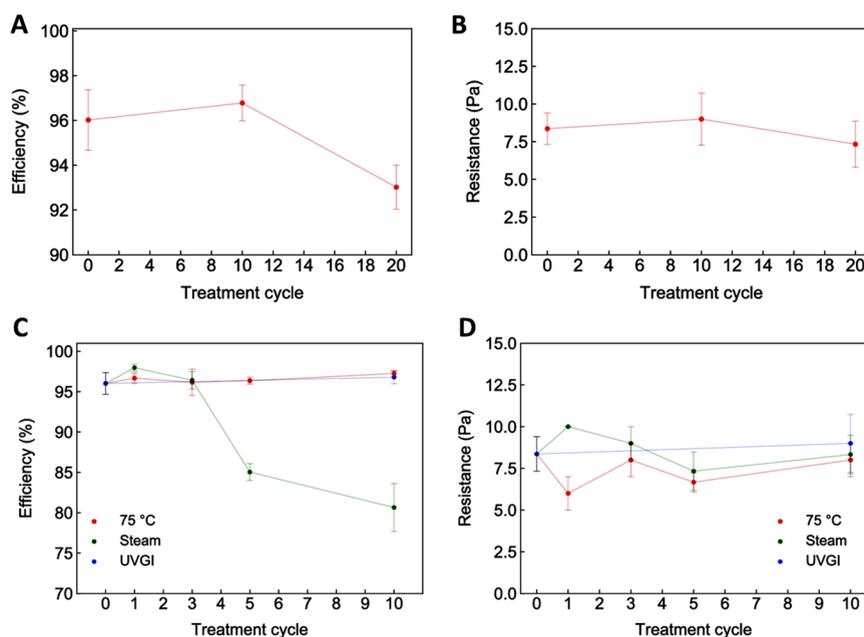


Figure 9. Effect of UVGI treatment on melt-blown filtration properties. (A) The filtration efficiency changes slightly until 10 treatment cycles of UVGI have passed, whereas for 20 treatment cycles, the efficiency decreases. (B) The pressure drop remains nearly the same. For the 10 treatment cycles of the melt-blown filter, (C) the efficiency decreases dramatically after using steam, meaning that humidity plays an important role during reprocessing. (D) The pressure drop remains nearly the same, suggesting that there is no structural change in the melt-blown material. Adapted with permission from ref 131. Copyright 2020 American Chemical Society.

When using a dry heating technique, mask decontamination using different temperatures for specific exposure times can effectively kill viruses while preserving the filter integrity for reuse. Typically, a temperature of 70 °C is maintained for 30 min.¹⁴⁸ According to a recent report, this method is applicable for two cycles to decontaminate SARS-CoV-2 from N95 masks without compromising the mask fit.¹⁴⁹ Applying higher temperatures also leads to shorter treatment times. However, the optimal parameters have yet to be determined.

6.2.2. UV Treatment. N95 mask decontamination by UV treatment has been employed in some hospital systems, and due to the precise requirements for this treatment, home UV treatment is not recommended.^{150,151} UV radiation can degrade polypropylene, so specific dosing protocols should be developed. The proper inactivation of SARS-CoV-2 with minimal mask degradation can be obtained by using a specific dosage and full surface area illumination.¹⁵¹ A recent report has shown that, with the appropriate dosage intensity, exposure times of up to 10 decontamination cycles are consistent with the NIOSH report, while the efficiency decays to 93% at 20 cycles.^{152,153} UV dosages up to 950 J/cm² conserve the filter efficiency, but the mechanical strength of filter media might be significantly affected.^{131,153} Liao et al. researched the effect of different disinfection processes on the performance efficiency of the N95 filter.¹³¹ The effects of ultraviolet germicidal irradiation (UVGI) treatment on melt-blown filtration properties are illustrated in Figure 9A,B.¹³¹ The filtration efficiency of the filter decreases after 20 treatment cycles, whereas 10 treatment cycles do not greatly affect their efficiency. The comparison of filtration efficiency levels after 10 treatment cycles using heat (without/with moisture) and UV is summarized in Figure 9C,D. From the comparison, it has been concluded that treating with dry heat and UV radiation is preferable to heat treatment with moisture in terms of maintaining the efficiency of the filter piece.

6.2.3. Hydrogen Peroxide Vaporization. The role of hydrogen peroxide vapor as a promising sterilization method is that it allows multiple cycles of N95 processing while leaving an acceptable level of mask filter integrity.¹⁴³ Nevertheless, this method is not applicable for N95 models containing cellulose. It is being used in industrial installations such as Battelle (up to 20 cycles) as well as individual hospitals via Sterrad (up to 2 cycles) or Steris equipment (up to 10 cycles).¹⁵⁴

The CDC recommended some viable methods, such as using steam and liquid hydrogen peroxide. Some methods are not recommended for reuse, such as bleaching and the use of alcohol, ethylene oxide, sanitizing wipes, soapy water, boiling, and broiling.¹⁵⁵ Moreover, N95 masks have many variations, including different strap materials and forms. Therefore, one method may work well for one mask type and not for others. However, the FDA revoked this emergency use authorization on June 30, 2021.¹⁴⁴

7. FACTORS AFFECTING MASK PERFORMANCE

Disposable N95 masks usually come with a shelf life of 5 years, meaning that they can be used within 5 years of the manufacturing date printed on the masks. Storage conditions might play a role in the efficiency of N95 masks. Over time, the quality of fit and seal of the masks can be affected due to the degradation of components such as the nose foam and strap materials. It is recommended to store the masks in their original packaging and keep them away from polluted areas, dust, extreme temperatures, excessive moisture, and damaging chemicals.¹⁵⁶ Moreover, the prolonged use, reuse, or reprocessing of masks affects their filtration integrity. Some general factors that affect N95 masks during use or reprocessing conditions are described in the following subsections.

7.1. Temperature. The recommended temperature for storing masks in the original packaging is from −20 to 30 °C. Nevertheless, during the decontamination process, the filtration

Table 5. Comparison of Physical Properties for Different Types of Masks or Respirators^a

	cloth mask	surgical mask	N95	N99	N100	R95	P100
type of mask or respirator/property							
medical application	no	yes	yes	yes	yes	yes	yes
face seal fit	loose/ill-fitting	loose/ill-fitting	tight fitting, seals over mouth and nose	tight fitting, seals over mouth and nose	tight fitting, seals over mouth and nose	tight fitting, seals over mouth and nose	comfortable face seal fit
user seal check requirement	no	no	yes; required every time it is put on	yes; required every time it is put on	yes; required every time it is put on	yes; required every time it is put on	yes; required every time it is put on
possibility of leakage	leakage through the fabric and around the edges of the mask	leakage around the edges of the mask between the face and mask	minimal leakage when properly used	minimal leakage when properly used	minimal leakage when properly used	leakage may occur if it is not fitted correctly	10% penetration of airborne particles, including the range of 4–30 nm, for face seal even after being properly sized, fitted, and worn ⁹¹
fluid resistance	not fluid-resistant	40–1300 nm	splashes at 80–160 mmHg; based on the type; not resistant to oil			yes (liquids without harmful vapors)	
valve	no	no	no	no	no	yes	yes
oil resistance	no	no	no	no	no	yes (somewhat resistant to oil)	yes (strongly resistant to oil)
pressure differential (Pa)	one layer cotton, 2.5; ¹⁶³ double layer cotton, 2.5 ¹⁶³	no gap, 2.5; ¹⁶³ with gap, 2.5 ¹⁶³	no gap, 2.2; ¹⁶³ with gap, 2.2 ¹⁶³				

^aInformation not cited in the table was collected from Mulder et al.¹⁶⁴

efficiency and air flow resistance remained intact at approximately 100 °C after a 10 min exposure time. When the temperature reaches over 125 °C, static decay occurs, causing a loss of filtration integrity.¹³¹ Therefore, under long-term storage, extreme temperatures can affect the filtration efficiency of the masks.

7.2. Relative Humidity (RH). The particle capturing capacity of N95 masks is not affected by humidity (when inhaling or exhaling, RH 95%) for a prolonged time.¹⁵⁷ However, humidity can play a part in degrading the charge of the electret filter media if a mask is continuously kept under higher humidity conditions for over 2 weeks.¹⁵⁸ Moreover, the breathing resistance increases over time under humid conditions even exceeding the NIOSH-approved maximum of 35 mm H₂O if worn in this condition over an 8 h working shift. For this reason, it is recommended to use multiple N95 masks over the workday in humid conditions.¹⁵⁷ Manufacturers suggested that the storage conditions for N95 disposable masks should not surpass 80% relative humidity.

7.3. Air Flow Rate. The air flow rate impinges on the particle penetration efficiency of N95 respirators. It has been determined that an increase in the flow rate above 85 L/min shows a higher penetration than a lower flow rate of 30 L/min. An increase in the flow rate through the respirator filter leads to a short residence time, which results in reduced diffusion and electrostatic particle deposition within the filter. Thus, a larger amount of submicrometer particles can permeate through the electret medium of N95 filters at a higher flow rate.¹³³

7.4. Contaminated Environment. Polluted environments with higher aerosol particle density can lead to a clogging effect on the N95 mask surface and thus can result in the reduction of the air stream through the layers. Therefore, the efficiency of filtration media decreases, resulting in an increase in breathing resistance.¹⁵⁹ Similarly, under humid conditions, breathing resistance seems to decrease as humidity contributes to a particle cake formation that creates channels so air can flow with less resistance.¹⁶⁰ Aerosol particle size is another factor to consider, and with increases in particle size, the filtering penetration of the masks is decreased.

7.5. Sunlight/UV. Exposure to sunlight/UV for a long time degrades the polymers used to develop disposable N95 masks, which ultimately reduces the respirator's ability to filter out infectious bioaerosols.¹⁵³

7.6. Chemicals. Exposure to some chemicals, such as alcohol, can damage the electrostatic charge from the filtration media and later decrease the filtration efficiency of the masks. The accumulation of chemical aerosols on the mask surface can lead to skin and/or respiratory irritation for the wearer.¹⁵⁵

8. COMPARISON WITH OTHER COMMERCIAL MASKS

Various types of commercial masks are available on the market, among which cloth and surgical masks are the most common. A comparison among the masks is made based on a range of factors, such as filtering competence, sealing efficiency, design, nature of particles, environment, etc. To understand this concern, the filtration efficiencies of different types of masks/respirators are discussed based on the following three key factors:

- (i) the size and characteristics of the targeted particle and factors primarily defining the extent of the filtration capacity;

- (ii) the nature of the environment, i.e., where the mask is being applied; and

- (iii) the types, design, and characteristics of masks/respirators and their interaction with filterable particles and the wearer's face.

The mask or respirator type is selected based on the form of particle to be collected. A variety of tests were performed to evaluate the performance of a mask or respirator, followed by a selection based on their penetration and filtration efficiency. Surgical masks are cleared by the FDA without any fit test and user seal check requirement, whereas N95 respirators are controlled and evaluated by NIOSH (filtration efficiency and pressure difference tests). OSHA requires user seal checks and fit testing per 1910.134 when respirators are required to be worn in the workplace.¹⁶¹ These specifications are described by CDC and NIOSH. For surgical mask clearance, manufacturers submit test results for fluid resistance, particle filtration efficiency [for polystyrene latex (PSL) and *Staphylococcus aureus* bacterial aerosol particles], bacterial filtration efficiency, fluid resistance, differential pressure, and flammability.^{140,162} For N95 respirators, NIOSH certification numbers may sometimes be submitted instead of efficiency testing using particulate filtration efficiency and bacterial filtration efficiency tests.¹⁴⁰ A combination of surgical mask and N95 FFR resulting in an advanced form of N95 mask named surgical N95 FFR is in compliance with FDA-approved fluid resistance (a method by ASTM F1862) and flammability parameters.¹⁶² However, there are no standard tests or requirements for cloth masks, and in general, they vary from country to country. Similarly, the product name keeps changing across the world while specifications remain constant. A comparison of the physical properties of different types of masks is shown in Table 5.

8.1. Comparison Based on the Size and Characteristics of the Targeted Particle. Various sources of pollutants produce differently sized particles that are captured at different efficiencies by cloth masks, surgical masks, N95 and N99 respirators, etc. For example, elements produced from polystyrene latex yield small particles from 30 to 500 nm.¹⁴² The sizes of T4 and *B. subtilis* bacteriophages are relatively larger and close to that of SARS coronavirus (100 nm). A comparative study revealed that the N95 respirator performed better at removing *B. subtilis* than T4 bacteriophages. Particles smaller than 100 nm (e.g., MS2 virions) were collected by both N95- and N99-type respirators. The penetration percentage of the N95 respirator approached that of the N99 respirator.¹³⁸ This finding implies that both smaller and larger biological particles are effectively filtered through the N95 mask. However, this investigation should be considered with caution and not generalized because the study was performed for a single model of N95 compared to two specific models of N99. It was also found that, for collecting large particles, a cloth mask is preferred compared to N95, although microscopic-sized viruses and bacteria are efficiently collected by N95,¹⁴² which is the primary concern of this Review. The diameter of the novel coronavirus is 125 nm; therefore, in this specific application, when selecting any filtering media, the size of the targeted particle as well as a good adjustment between the particle and filtering media should be our first concern. Selecting an N95 respirator for use in an environment in which most of the particles are expected to be either mist or dust types is not a smart decision and may create a supply shortage of this specialized mask in the case of high demand due to something

Table 6. Particle Penetration Efficiency of Various Commercial Masks/Respirators

type of mask/ respirator	particle size and penetration efficiency at 30 L/min	particle size and penetration efficiency at 85 L/min	particle under examination	ref
dust-mist-type respirator	40 nm (11%); 130 nm (6%)			133
N99	20–90 nm ($0.96 \pm 0.12\%$); 20–90 nm ($1.03 \pm 0.55\%$)	20–90 nm (<3%); 20–90 nm ($3.28 \pm 0.20\%$); 20–90 nm ($3.43 \pm 0.86\%$)	MS2 virions	138
Surgical mask	40 nm (>20%) 130 nm (<15%)			133 133
NIOSH-approved N95	20–90 nm ($1.69 \pm 0.38\%$)	10–70 nm (20.5–84.5%) 20–90 nm ($3.45 \pm 0.48\%$)	MS2 virions MS2 virions	7 138
	30–100 nm (~2.25%)	30–100 nm (~3.5–3.7%)		133
	130 nm (~1.8%)	130 nm (~2.0%)		133
	100 nm ($0.58 \pm 0.22\%$)	100 nm ($1.90 \pm 0.19\%$)	<i>Bacillus subtilis</i> phage	138
	100 nm ($0.23 \pm 0.01\%$)	100 nm ($0.95 \pm 0.11\%$)	T4 phage	138
NIOSH-approved R95	30–100 nm (~2.25%)	30–100 nm (~3.5–3.7%)		133
	130 nm (~1.8%)	130 nm (~2.0%)		133

like a pandemic. Particles of this type and size range can easily be filtered out by cloth masks or dust and mist respirators that cost less than the N95-type respirator. Hence, the workplace conditions should be considered to recommend a cloth mask or N95 respirator for the protection from an airborne hazard.

FFRs show a better performance than surgical masks in collecting virus particles. This comparison was supported by a parameter called a reduction factor, which describes the exposure to live aerosolized influenza virus as the ratio of the particle concentration inside and outside for each mask. Gawn et al. found that a properly adjusted FFR exhibited a mean reduction factor in exposure of 100, while a surgical mask showed a mean reduction factor of 6.¹⁶⁵ From this standpoint, an FFR is considered a more suitable agent for eliminating influenza virus than a surgical mask. Another significant factor to evaluate the performance of any mask is the protection factor. Any FFR that could be used in personal protective equipment to shield from COVID-19 should have a protection factor greater than or equal to 10. Unfortunately, not every mask is capable of providing this desired level of protection. In one study, nearly 29% of N95 respirators and 100% of surgical masks were found to show a protection factor <10 (the protection factor set by OSHA for that type of mask),^{100,166} which suggested that not every N95 would offer the expected level of protection against bacteria and viruses. However, this study implies that N95 can be selected to give a substantial level of protection from the virus compared to any type of surgical mask. To prevent acute respiratory infection, another group of researchers did not find adequate evidence to uniquely establish that N95 respirators are superior to surgical masks as protection for healthcare workers in clinical settings.¹⁶⁷ Nevertheless, in laboratory settings, they indicated that N95 respirators offered better protection than surgical masks.¹⁶⁷ When comparing the effectiveness of homemade cloth masks to medical masks in real clinical situations, the effectiveness of surgical masks (with a particle penetration percentage of 44%) was superior to that of cloth masks (particle penetration percentage of 97%).¹⁶⁸

8.2. Comparison Based on the Nature of the Environment. At a lower air flow rate (~8 L/h), a surgical mask, N95 mask, and cloth mask with an exhalation valve show similar separation efficiencies.¹⁴² In terms of removing aerosols carrying bacteria and viruses, N95 and R95 perform better than surgical masks and mist- and dust-type respirators (Table 6).¹³³

According to the FDA, fluid resistance is another important parameter for evaluating the performance of the N95 mask in comparison with the popular surgical mask and advanced surgical N95 FFRs. This test has a significant impact on the overall efficiency of the mask when it will be used under extreme conditions to shield medical service providers from inhaling infectious aerosols and splashes/sprays of body fluids while providing healthcare facilities.¹⁶² Following the ASTM F1862 method, two different velocities were selected (450 and 635 cm/s), and the N95 FFR, surgical mask, and surgical N95 FFR passed the test (Table 7). Nonetheless, the extent of their passing rate could vary depending on the source and material of the mask under examination.

8.3. Comparison Based on the Types, Design, and Characteristics of Masks/Respirators. Usually, masks (e.g., cloth masks and surgical masks) are loose-fitting equipment for providing minimum protection from airborne particles, whereas most of the respirators are tightly fitted to the face, which prevents the individual user from inhaling toxic particulates and aerosols (dust, smoke, and mist). Moreover, it protects the wearer from airborne infectious agents. Filtering facepiece respirators consist of a facepiece and a filtering device. Some respirators are equipped with an exhalation valve to provide additional comfort to the user by preventing condensation inside the mask and misting on the glasses and by helping the user breathe out easily. Occasionally, the most common fabric mask is also designed with this kind of exhalation valve for better comfort. It is also noted that respirators can be disposable or reusable, and in many cases (e.g., reusable respirators with replaceable cartridges), the filter cartridge can be replaced when breathing resistance increases, odors are detected, or an ESL indicator on the cartridge changes color.

A cloth mask is the most widely used mask, particularly in developing countries. This is because they are inexpensive, locally available, and washable. This cloth-based mask usually consists of a synthetic or natural textile material supported by elastic straps, which can be worn behind the head or over the ears to maintain fit-to-face adjustment. A cloth or fabric mask may be available with or without an exhalation valve. A cloth mask with an exhalation valve performs better compared to that without an exhalation valve for polystyrene latex (PSL) particles with a size of 30–2500 nm.¹⁴² For larger particles (1000–2500 nm), the mask shows a filtration efficiency of up to 94%, which is

Table 7. Filtration Efficiencies of Various Commercial Masks or Respirators

particle type or test type/mask or respirator type	N95 FFR	surgical N95 FFR	N99	surgical mask	cloth mask with an exhaust valve	P100
NaCl particle test	NIOSH-approved polydisperse NaCl aerosol; count median P.D., ^a 75 ± 20 nm; F.E., ^b 98.15–99.68% ¹⁴⁰	NIOSH-approved polydisperse NaCl aerosol; count median P.D., 75 ± 20 nm; F.E., 98.27–99.93% ¹⁴⁰	NaCl aerosol, median P.D., 75 nm; F.E., 99.634 ± 0.024% ¹⁶⁹	NIOSH-approved polydisperse NaCl aerosol; count median P.D., 75 ± 20 nm; F.E., 54.74–88.4% ¹⁴⁰		
polystyrene latex (PSL) particle test	monodisperse PSL >750 nm F.E., ≥99.5%; and 100–300 nm F.E., ≥95% (flow rate, 85 L/min) ¹³⁵			low viral loading; F.E., >95% (flow rate, 85 L/min) ¹³⁵	particle size, 30, 100, and 500 nm; F.E., 80–90% ¹⁴²	
airborne bacterium test	PSL >750 nm F.E., ≥99.5%; and 100–300 nm F.E., ≥95% (flow rate, 85 L/min) ¹³⁵			ratio, 4.8–5.8 (40 nm ≤ P.D. ≤ 100 nm) ¹¹⁵		size, 4–30 nm; F.E., >99.97% ⁹¹
<i>in vivo</i> filtration tests (KCl solution)	low viral loading; F.E., >97% (flow rate, 85 L/min) ¹³⁵					
face seal leakage-to-filter ratio	ratio, 7–20 (40 nm ≤ P.D. ≤ 100 nm) ¹¹⁵					
monodisperse siliver particle filtration efficiency	particle size, 4–30 nm; F.E., >95% ⁹¹					
particulate filtration efficiency (PFE) test	F.E., 99.74–99.99% (particle size and specification, 100 nm size polystyrene latex particles) ¹⁴⁰	F.E., 99.84–99.98% (particle size and specification, 100 nm size polystyrene latex) ¹⁴⁰		F.E., 98.26–98.66% (particle size and specification, 100 nm size polystyrene latex) ¹⁴⁰		
bacterial filtration efficiency (BFE)	F.E., 99.62–99.9% (particle size and specification, 3000 nm size particles containing <i>Staphylococcus aureus</i> bacteria) ¹⁴⁰	F.E., 99.80–99.90% (particle size and specification, 3000 nm size particles containing <i>Staphylococcus aureus</i> bacteria) ¹⁴⁰		F.E., 97.48–99.80% (particle size and specification, 3000 nm size particles containing <i>Staphylococcus aureus</i> bacteria) ¹⁴⁰		
viral filtration efficiency (VFE)	F.E., 99.8–99.90% (particle size and specification, ~3000 nm size particles containing phiX 174 as the challenge virus and <i>Escherichia coli</i> as the host) ¹⁴⁰	F.E., 99.88–99.90% (particle size and specification, ~3000 nm size particles containing phiX 174 as the challenge virus and <i>Escherichia coli</i> as the host) ¹⁴⁰	F.E., 97.12–99.88% (particle size and specification, ~3000 nm size particles containing phiX 174 as the challenge virus and <i>Escherichia coli</i> as the host) ¹⁶⁰	F.E., 95–100% at 450 cm/s ¹⁶²		
fluid resistance test	F.E., 80–100% at 450 cm/s ¹⁶²	F.E., 96–100% at 450 cm/s ¹⁶²		F.E., 65–100% at 635 cm/s ¹⁶²		
	F.E., 64–100% at 635 cm/s ¹⁶²	F.E., 92–100% at 635 cm/s ¹⁶²				

^aP.D.: particle diameter. ^bF.E.: filtration efficiency.

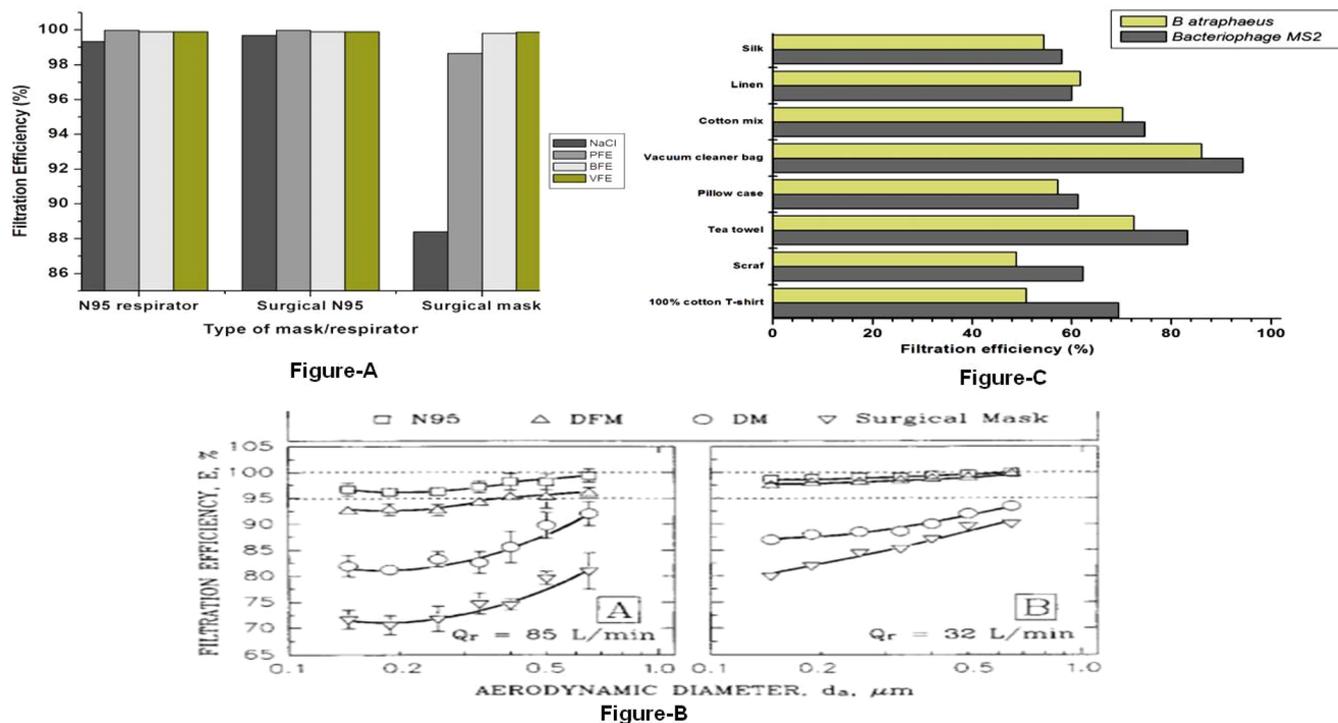


Figure 10. Filtering efficiency of various devices under variable working conditions and particles. (A) Filtration efficiency of three different masks/respirators in filtering out NaCl, particles, bacteria, and viruses. Adapted with permission from ref 140. Copyright 2017 Taylor & Francis. (B) Filtration efficiency of an N95 respirator; dust-, fume-, and mist-type respirator; dust- and mist-type respirator; and surgical mask (SM), tested with NaCl particles under two different flow conditions. Adapted with permission from ref 26. Copyright 1998 Taylor & Francis. (C) Filtration efficiency of cloth masks made from different fabrics in filtering out two specific biological particles. Adapted with permission from ref 146. Copyright 2013 Cambridge University Press.

much higher than the efficiency when collecting smaller particles (30–500 nm). Moreover, for particles of approximately 2500 nm, cloth masks are marginally advantageous compared to the standard N95.¹⁴² In summary, N95 respirators possess two advantages over simple cloth or surgical masks. First, this mask is capable of filtering more than 95% of 300 nm particles (smaller than the 5000 nm size of large droplets, which are created during coughing, talking, and sneezing and usually spread viruses). Second, the N95 respirators offer better fitting over surgical masks by preventing leakage around the mask.⁷²

For the practical use of a respirator or mask, it is always preferred that the testing conditions when respirators are approved by NIOSH resemble a real environment. Various factors determine the effectiveness of the mask in terms of application, for example, the physical posture of the wearer and the capacity of unwanted particles to penetrate the mask vicinity through leakage (which may be due to improper attachment to the face or by the random quick movement of the wearer). This factor was calculated by using a ratio named face seal leakage-to-filter ratio. The face seal leakage-to-filter ratio is a ratio of two different penetration rates: (i) particles penetrating through the face seal and (ii) particles penetrating the filter media. The higher the ratio is, the higher the possibility of penetration via face seal leakage. The number of particles penetrating through the face seal leakage of a tested N95 respirator/surgical mask far exceeded the number of those penetrating through the filter medium.¹¹⁵ Therefore, the ratio will be much higher than 1. Moreover, for the N95 respirator (7–20), the ratio was significantly higher than the ratio possessed by surgical masks (4.8–5.8) in terms of variable size particles (30–1000 nm).

Many researchers have evaluated the efficiency of filtering devices under conditions differing in terms of particle type, particle flow rate, and filter material selection.^{26,140,146} Figure 10 illustrates some of the studies conducted by researchers to provide a direction when choosing the best possible filtering media for users.

Figure 10A shows the filtration efficiency values for the N95 FFR, surgical N95 FFR, and SM models using NIOSH-approved NaCl, bacterial filtering efficiency (BFE), viral filtration efficiency (VFE), and particulate filtering efficiency (PFE) methods. Different models of mask/respirators were evaluated, and the figure represents the median filtering efficiency. Both the N95 FFR and surgical N95 models showed more than 98% filtration efficiency. However, both respirators showed a NaCl filtering efficiency that was slightly lower than that observed for bacteria, viruses, and particulate matter. Similarly, several models of surgical masks displayed the lowest filtration efficiency for NaCl particles, which was below 90%.¹⁴⁰

Figure 10B shows the differences in filtering out the polydisperse NaCl (most penetrating size 100–300 nm) by four masks/respirators, i.e., N95; dust-, fume-, and mist-type respirators (DFMs); dust- and mist-type respirators (DMs); and surgical masks (SMs), under two different flow rates. The NaCl particles were prepared by nebulization of NaCl solution. The minimum efficiencies observed at the most penetrating particle size were approximately 96%, 92%, 82%, and 71% for the N95 respirator, DFM respirator, DM respirator, and surgical mask, respectively. Thus, it was concluded that only the N95 respirator satisfies the minimum 95% efficiency requirement under standardized regulations. All of these results were obtained at a higher flow rate (85 L/min). However, the performance of the

specimens was also examined at another flow rate of 32 L/min, which is close to the 30 L/min that represents a low to moderate workload. At this particular flow rate, both the N95 and SM showed efficiencies for all sizes of particles of above 95%. Moreover, the filtration efficiency of the other two types of respirators (DFM and DM) was also improved compared to the efficiency reported at 85 L/min. Additionally, at the smallest tested particle size (aerodynamic diameter ca. 150 nm), the N95 respirator had the highest filtration efficiency (98.8%), and the surgical mask showed the lowest filtration efficiency (80%), whereas the minimum measured efficiency of the DFM respirator was approximately 97%. Thus, this DFM respirator had more than the minimum 95% collection efficiency when the workload (32 L/min) was low, but it did not fulfill the certification requirement at a higher flow rate of 85 L/min.²⁶ It needs to be mentioned that DFM and DM respirators are no longer approved by NIOSH from 1995 when 42 CFR 84 was approved. Depending on the size of the particle and its concentration in the environment, when selecting respiratory protection, a balance between the cost and selectivity of the filtering device should be maintained. However, there is always a chance of less than or equal to 5% for airborne particles to penetrate through the filter medium of the mask or respirator, and this should be taken into consideration when designing the next generation of filtering facepiece devices.

Figure 10C shows the filtration efficiency of various types of cloth masks made from 8 different household fabrics to collect the microbial aerosol particles (*B. atrophaeus* and MS2 bacteriophage). The mask made from a vacuum cleaner bag showed result comparable to that of the surgical mask in filtering out the MS2 bacteriophage. However, the high thickness and stiffness of the vacuum cleaner bag material created a high pressure drop across the material, which made it inappropriate for use in a face mask. Similarly, the mask prepared from tea towel fabric also exhibited a high pressure drop but nevertheless showed a relatively high filtration efficiency with both *B. atrophaeus* and MS2 bacteriophage. A higher pressure drop was also observed when a double layer of 100% cotton T-shirt and pillowcase fabric was used; however, they provided a very good fit to the wearer. Masks prepared from silk and linen material showed the overall lowest filtration efficiency against these two biological particles.¹⁴⁶

As discussed in this section, cloth masks and surgical masks are comfortable to wear compared to N95 respirators. On the other hand, N95 respirators provide better fit and protection than cloth masks and surgical masks. The penetration of particulates and aerosols through cloth masks is much higher compared to N95 respirators; hence, using a cloth mask will not be effective to protect from these particles.¹⁷⁰ Both the surgical masks and N95 respirators perform well against airborne particles; however, the latter perform better with lower particulates and aerosol permeability. Nevertheless, N95 respirators should be used carefully as they may not always provide sufficient safety against aerosol particles smaller than 300 nm.³⁸

9. LIMITATIONS, CONCERNS, AND SCOPE OF IMPROVED PERFORMANCE EFFICIENCY

To overcome the challenges and limitations of using N95 respirators, we suggest some potential directions for future research in this field.

Many researchers have concluded that most of the penetrating particles enter through face seal leakage rather than the filter

medium of the N95 respirators.¹¹⁵ Minimum leakage with better respiratory efficiency can be confirmed through the proper fitting of the respirator to the user's face. Unfortunately, many commercial N95 masks are subject to poor fit problems due to their complicated design. Hence, appropriate respirator design is needed. Designing a mask with a focus on wearer age, face shape, and the site where it will be used may improve the overall performance and popularity of the N95 mask. However, very few manufacturers have considered the usability and demand for this mask among different groups of people, especially when a hospital is providing services to all types of people of different ages; for example, children arthrometric facial features may be different from the standard face shapes of adults used by respirator manufacturer's when designing their products. Considering the COVID-19 situation, there is a possibility of affecting the other patients, doctors, or nurses if a respirator is not well-fitted to the face of the infected person. The most common reason for this type of transmission is contamination of the environment by particle leakage from the face seal of the infected person due to an incorrectly fitted or selected mask. However, additional study is needed to identify the exact reason for the leakage and its influence on the transmission of the viruses. In addition, there is a possibility that these viruses penetrate through the mask in the form of liquid diffusion by a capillary action, particularly since the exhaled air (by the wearer) most likely wets the mask.¹³⁵ The higher percentage of moisture in the exhaled air causes water vapor to be trapped in the fibers of the mask.^{135,171} Moreover, the droplets that are expelled when speaking accelerate the wetting process, and thus, the action of breathing facilitates the penetration. During recurring breathing actions, a mask collects viruses, particularly when exposed to contaminated droplets in the air.¹³⁵ This kind of humid environment inside the respirator also results in less comfort for the N95 respirator wearer. Using an exhalation valve will give comfort to the user for breathing and minimize humidity inside the mask. However, this exhalation valve is also responsible for polluting the environment when it is opened to discard the particles outside the respiratory system. Moreover, adding this extra piece may increase the overall price of the respirator. Therefore, developing an appropriate design is necessary to minimize these problems.

The primary goal of using any respirator or mask is to provide the desired level of protection to the wearer or to the environment to prevent contamination by unwanted particles. On this point, OSHA has set the assigned protection factor (APF) at 10 for disposable FFRs irrespective of filter designation when used in a complete respiratory program, including proper FFR selection and fit testing.¹⁶⁶ Furthermore, any leakage between the N95 respirator and the face of the wearer may make this respirator more vulnerable to particle penetration through leakage. This penetration through leakage changes with the particle size (from <3% for 1000 nm particles to 5% for 100 nm particles), which actually constrains its application for collecting biological and nonbiological particles of variable range.¹¹⁵ Moreover, a mask is fabricated by using layers of nonwoven fiber, which can release microfibers in the vicinity of a humid and sweaty environment inside of the respirator, creating the possibility of being affected by several bronchial diseases in the long run.^{172,173} Some current approaches of using an exhalation valve with masks are discouraged by researchers since exhaled air directly released into the environment would favor the spreading of the coronavirus.¹⁷⁴ This issue has become a major concern for manufacturers. Thus, balancing user comfort

with cost and complete safety is a key challenge for researchers in designing the N95 respirator for SARS-COV-2 removal.

In terms of internal design, several approaches can improve the usability and effectiveness of the masks. Introducing a high-efficiency filter (i.e., N100, R100, P100) as a separate layer may improve the lifetime and effectiveness of the respirator. Another option can be the addition of a disposable surgical mask type layer on the outer surface of the N95 mask, which will improve the collection efficiency of the respirator without creating breathing resistance for the wearers, as well as improving long-term mask usability. Moreover, an interlayer fiber with lower unwanted particle permeability and better air permeability will also improve the collection efficiency of the respirator. However, a detailed investigation is needed to choose the material and design of the interlayer without compromising breathing quality. Additionally, producing a water-repellent shield on the outside and inside of the N95 respirator will increase its moisture repellency and overall efficiency.¹³⁵

Materials such as natural silk, chiffon weave (90% polyester, 10% Spandex fabric), and flannel (65% cotton, 35% polyester blend) can likely provide a good electrostatic filtering of particles.¹⁶³ Konda et al. found good protection across a 10–6000 nm range of particulates by using four layers of silk.¹⁶³ Combining layers to form hybrid masks and leveraging mechanical and electrostatic filtering may be an efficient approach, e.g., a high-thread-count cotton combined with two layers of natural silk or chiffon or two layers of cotton sandwiching cotton–polyester batting. Konda et al. found promising filtration efficiency (>80% for particles sized <300 nm and >90% for particles sized >300 nm) in all of these cases. In particular, a cotton quilt with batting provided a superior performance of $96 \pm 2\%$ (10–300 nm) and $96.1 \pm 0.3\%$ (300–6000 nm) at small particle sizes because of its highly tangled fibrous nature. These types of hybrid masks could be a temporary solution in the case of high demand for N95 masks. Moreover, if the cost of these types of masks can be lowered compared to that of N95 masks, they can be recommended for mass use after careful investigation in terms of collection efficiency, fit, breathing resistance, etc., especially for people who are at high risk.

Increasing the electrostatic charge in an N95 mask is a potential way to increase the efficiency of the mask. One of the options can be redesigning the fibrous materials of the mask's middle layer. Different fiber-forming polymers that possess higher charge densities can be used to fabricate fibrous mask filters. Additional electrical charge can be provided to these materials by applying an external electric field. Moreover, the blending of different polymers or the incorporation of suitable additives may also help to attain the desired electrostatic properties. Additionally, the performance of the mask can be improved by changing the environment where the mask will be used. This kind of change is practical when healthcare providers work in environments with a predetermined air quality. One way to improve the performance of the respirator or mask is by charging the ions in the vicinity of the respirators to produce a protective layer of the same charge on the outer surface of the respirator that will repel the virus from entering. In general, this finding supports the introduction of an electrostatic shield on the outer surface of the mask.¹⁷⁵

Reusing N95 masks could be the best option for mitigating the crisis of uninterrupted supply to healthcare providers during a pandemic situation. However, several reports claim that the mask loses its performance efficiency during most disinfection

processes.¹³¹ One of the reasons for this declining efficiency is the removal or neutralization of surface charges during disinfection treatment. Sterilization by soapy water is prohibited for this mask; rather, scientists prefer that users clean their hands frequently with soap.¹⁷⁶ Another popular method for mask reuse is to perform heat treatment, although the dry heat deactivation of this virus has not yet been reported by researchers. Nevertheless, heat (≤ 85 °C) under various humidities ($\leq 100\%$ relative humidity, RH) has been reported as the most promising, nondestructive, and user-friendly method for disinfecting N95 respirators without compromising their performance efficiency over at least 50 cycles of heat treatment.^{131,174} The use of available sources of radiation is another possible means of disinfecting used masks. In many cases, the strap and facepiece may be damaged by UV–C-type radiation at a high dose (≥ 120 J/cm).¹⁷⁷ Moreover, UV–C is unable to destroy trapped viruses at the inner part of the mask, leaving the possibility of affecting the user at the next use. Apart from the limitations of UV radiation, the use of γ radiation or UVGI could be a promising method to regenerate respirators without degrading their polymer materials.^{150,178–180} CDC warns that “UVGI is unlikely to kill all the viruses and bacteria on a filtering facepiece respirator due to shadow effects produced by the multiple layers of the filtering facepiece respirator construction.”¹⁸¹ In terms of using chemical methods, hydrogen peroxide is capable of disinfecting the respirator, and this method also comes with a successful post-treatment fit test result.¹⁸² Hydrogen peroxide vapor inactivates the coronavirus and does not degrade the effectiveness of the filter, fit, or straps even after 20 cycles of treatment. One of the best possible methods of reusing N95 respirators for up to 72 cycles without damaging the mechanical properties and filtration efficiency is by applying ozone under controlled conditions.^{132,180} However, workers who disinfect masks using ozone can experience serious health issues, thereby confining the use of this method on a commercial scale. Ozone chambers with appropriate engineered controls can be used safely to disinfect FFR by eliminating the source of exposure to the workers. Many of these processes may affect the electrostatic charge of the filter medium. However, a simple technique can be developed to electrify the mask with an external electric field to restore the efficiency to a greater extent. Another issue involved with the reuse of the respirators is their fitting performance after the first use, because fitting factors affect the overall protection performance of these respirators. There is evidence of a drop in the average fit factor of the best fitting respirator worn by participants after nursing procedures.²⁷ One possible way to perform this regeneration could involve multiple processing steps instead of a single step. For example, radiation such as UV–C could be applied at the beginning of the process while hiding the vulnerable strap, and then, a short-term ozone treatment can be introduced to eliminate the rest of the viruses from both the straps and inner and outer sections of the mask. By following this short period of ozone treatment, the risk of health damage to workers can be minimized compared to single-step long-term exposure. Moreover, successive applications of nonreactive approaches would not hamper the overall effectiveness of the single treatment methods. Above all, when suggesting any disinfection process, the researcher should also carefully evaluate any possible effect of the process on respirator fitting factors.

The performance evaluation process should be updated. To date, N95 masks have been tested using nonbiologic particles as challenge aerosols, although respirator use is often aimed at

reducing exposure to biologic particles. Moreover, manikin-based NIOSH certification testing eliminates respirator–face leakage when a subject wears a personal respiratory protection device. However, this protocol fails to mimic real conditions during human usage, such as displacement of masks due to irregular body movements, facial muscle movements, or the accumulation of aqueous droplets from the mouth. Hence, in real life, leaks may lead to considerably increased particle penetration. All of these factors should be incorporated in the NIOSH certification testing requirement to evaluate the real performance efficiency of the masks. Current international standards on efficiency tests for respirators focus on measuring the minimum efficiency at the most penetrating particle size. However, some commercial test systems that provide the ability to measure particles down to the 15 nm range could be used to improve the testing methods for particles in the single-digit nanometers.³⁴ The development of standard test methods to determine the efficiency of filtration media against airborne particles down to the single-digit nanometer range is a vital need for the more precise control of the performance evaluation technique.

A respirator or mask is designed to collect particles of variable diameters. The collection performance of the respirator largely depends on the density of particulates and aerosol in the air. The excessive collected particles may create a barrier to the filtration performance of the filter media. Notably, masks used in more highly concentrated areas of nanosized viruses or bacteria, in a closed environment, or under heavy workload conditions may not provide desirable protection to the wearers. Under these circumstances, the reaerosolization of the virus could be a vital issue in some workspaces. Usually, no reaerosolization from the N95 respirator occurs under normal working conditions. However, there is considerable evidence of the aerosolization of bacteria and other particles from the N95 respirator when it is exposed to conditions such as sneezing and coughing or higher-velocity exhalation associated with heavy working conditions, especially as the respirator is loaded with aerosols.²² Reaerosolization may happen when the wearer coughs or sneezes at an exhalation air velocity exceeding 25 times the breathing velocity through the respirator under heavy workload conditions. At these conditions, there is a chance that particles, especially larger particles, will go back to the environment from the mask (previously entrapped). A negative air pressure in the room that is used as an isolation technique in hospitals may facilitate reaerosolization even faster. Manufacturing engineers may emphasize redesigning respirators to mitigate these problems. Using fabrics suitable for the immobilization of the virus-carrying aerosol could be one option. Nonwoven fabric with more lyophilic properties may offer a better collection capability for virus-containing particles and should be less prone to reaerosolization. Moreover, the coronavirus is an enveloped virus, and its lipid bilayer is its primary determinant of survival, because viruses with higher lipid contents persist better under lower-humidity conditions.^{22,96} Introducing humectants to fabric materials to increase their moisture-retaining properties without affecting the respirator's performance may be helpful for reducing the lifespan of the virus particles.

Plasma treatment is a promising postprocessing method that offers the chances to achieve unique surface functionalization on various substrates.^{182–184} The surface of hydrophilic nonwoven materials can be modified by plasma treatment to obtain superhydrophobic properties with an enhanced functional performance of the final product.^{184,185} This treatment is an

environmentally friendly process with low production cost. This modification occurs only on the upper molecular layers of the substrates without changing the material's bulk properties; hence, it could easily be employed in applications such as sterilization, enhancing hydrophobicity and antimicrobial properties, and improving the adhesion properties of nonwoven fabrics. This method should be investigated for disinfecting used respirators for reuse.

Due to the global shortage, the reuse and long-term wear of respirators have augmented the concern of bacterial contamination. Antimicrobial coatings of the surface of the respirator can offer a remedy to this problem.^{184,186–188} Kumaran et al. found excellent antibacterial activities of surface-coated N95 respirators, independent of the transmission modes (droplets and aerosols), medium composition, and wetting properties. Zhong et al. developed inspiring superhydrophobic coated N95 respirators containing silver nanoparticles, possessing significantly better protection than existing ones.¹⁸⁴ The synergistic effect of a superhydrophobic coating and the presence of silver nanoparticles prohibits aqueous respiration droplets from accumulating on the respirator surfaces as well as disinfection toward microbes. These results motivate researchers to combine an antimicrobial and superhydrophobic coating and/or plasma treatment to develop better respirators to fight the COVID-19 pandemic.

There is concern about the risks of misuse or injury, and the high breathing resistance of the respirators would make it difficult for children to wear them for long periods.¹³⁹ Moreover, adult N95 face masks show intrinsic penetration (15–50%) of submicron-sized particles for pediatric use.¹³⁹ Because there is a lack of other options for children at present, face mask design should be extended for pediatric use, which reduces the likelihood of infection during emergency situations. As suggested by Guha et al., developing masks meant for the specific anthropometric features of children is a possible alternative for increasing the level of protection.¹³⁹

10. CONCLUDING REMARKS

The filtration of airborne nanoparticles is crucial to reducing the transmission of airborne viral particles through inhalation. A review of the literature shows that significant progress has been made in understanding nanoparticle filtration in the field of airborne disease protection in recent years. Although there are reports on a lack of clear superiority of N95 respirators over face masks in several studies, the majority of researchers claimed better performance for N95 respirators over face masks or surgical masks, if properly used and in the absence of seal leakage, no eye protection being used, or in infections from sources outside the healthcare setting. After the extensive literature review presented here, we believe that there are many potential paths to improving the performance efficiency of N95 masks from the manufacturing stage to the reuse stage. The suggestions made here would be helpful for deciding the best strategy to support the resilience of healthcare systems confronting the potentially catastrophic SARS-CoV-2 pandemic as well as preparing for better control over any future disease outbreak. We hope that this Review will be helpful to those managing the present crisis by improving the reuse efficiency of N95 respirators.

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